Filed pursuant to rule 424(b)(4)
Registration No. 333-257444

PROSPECTUS

9,000,000 Shares

COMMON STOCK

We are offering 9,000,000 shares of common stock in this offering. This is our initial public offering of our common stock.

Prior to this offering, there has been no public market for our shares. The initial public offering price is $8.00 per share. Our common stock has been approved for listing on The Nasdaq Global Market under the symbol “CADL.”

We are an “emerging growth company” under the federal securities laws and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and for future filings.

Investing in our common stock involves a high degree of risk. See “Risk Factors” beginning on page 10 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission approved or disapproved of the securities that may be offered under this prospectus, nor have any of these organizations determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	PER SHARE	TOTAL
Public offering price	$ 8.00	$72,000,000
Underwriting discounts and commissions (1)	$ 0.56	$ 5,040,000
Proceeds to us before expenses	$ 7.44	$66,960,000

(1) We refer you to “Underwriting” beginning on page 184 for additional information regarding underwriting compensation.

Delivery of the shares of common stock will be made on or about July 29, 2021.

We have granted the underwriters an option for a period of 30 days to purchase up to an additional 1,350,000 shares of our common stock. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be $5.8 million, and the total proceeds to us, before expenses, will be $77.0 million.

Joint Book-Running Managers

Jefferies **Credit Suisse** **BMO Capital Markets** **UBS Investment Bank**

The date of this prospectus is July 26, 2021

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Through and including August 20, 2021 (25 days after the commencement of this offering), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the obligation of dealers to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

We have not, and the underwriters have not, authorized anyone to provide any information or to make any representation other than those contained in this prospectus, any amendment or supplement to this prospectus or any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares of common stock offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus, any amendment or supplement to this prospectus or any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: We have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside the United States.

The market data and certain other statistical information used throughout this prospectus are based on independent industry publications, governmental publications, reports by market research firms, or other independent sources that we believe to be reliable sources. Industry publications and third-party research, surveys, and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We are responsible for all of the disclosure contained in this prospectus, and we believe that these sources are reliable; however, we have not independently verified the information contained in such publications. While we are not aware of any misstatements regarding any third-party information presented in this prospectus, their estimates, in particular, as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties, and are subject to change based on various factors, including those discussed under the section entitled “Risk Factors” and elsewhere in this prospectus. Some data are also based on our good faith estimates.

This prospectus contains forward-looking statements that are subject to a number of risks and uncertainties, many of which are beyond our control. See “Risk Factors” and “Special Note Regarding Forward-Looking Statements.”

Trademarks and Trade Names

We own or have rights to various trademarks, service marks and trade names, including our company name, that we use in connection with the operation of our business. This prospectus may also contain trademarks, service marks and trade names of third parties, which are the property of their respective owners. Our use or display of third parties’ trademarks, service marks, trade names or products in this prospectus is not intended to, and does not imply a relationship with, or endorsement or sponsorship by us. Solely for convenience, the trademarks, service marks and trade names referred to in this prospectus may appear without the ®, TM or SM symbols, but the omission of such references is not intended to, and should not be construed to, indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable owner of these trademarks, service marks and trade names.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus, including our consolidated financial statements and the related notes included elsewhere in this prospectus. You should also consider, among other things, the matters described under "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," in each case appearing elsewhere in this prospectus. Unless the context otherwise requires, the terms "Candel," "we," "us," "our," "our company," "the Company," "the Registrant" and "our business" in this prospectus refer to Candel Therapeutics, Inc.

Overview

We are a late clinical stage biopharmaceutical company focused on helping patients fight cancer with oncolytic viral immunotherapies. Our engineered viruses are designed to induce immunogenic death through direct viral-mediated cytotoxicity in cancer cells, thus releasing tumor neo-antigens and creating a pro-inflammatory microenvironment at the site of injection. Our approach combines an in-depth knowledge of viral immunotherapy with extensive clinical experience across a wide range of indications. Based on the broad range of data that we have generated from our preclinical models and clinical trials using our approach, we have observed what we believe to be systemic immune response against locally injected tumors and their distant metastases. We have established two oncolytic viral immunotherapy platforms based on novel, genetically modified adenovirus and herpes simplex virus (HSV) constructs. In our clinical results to date from CAN-2409, our lead product candidate from our adenovirus platform, and CAN-3110, our lead product candidate from our HSV platform, we have observed that these candidates may have the potential to address significant unmet patient need and improve clinical outcomes in novel indications across broader patient populations.

Our most advanced product candidate, CAN-2409, is an off-the-shelf adenovirus product candidate combined with the prodrug valacyclovir that has generated promising clinical activity across a range of solid tumor indications, including our lead indication of prostate cancer. We are currently conducting, as part of our most advanced CAN-2409 program, a Phase 3 clinical trial in the United States under a Special Protocol Assessment, or SPA, with the FDA for CAN-2409 in combination with the prodrug valacyclovir in patients with newly diagnosed localized prostate cancer who have an intermediate or high-risk for progression. We expect to complete enrollment for this trial in the third quarter of 2021 with a final data readout in 2024. We are also evaluating CAN-2409 in newly diagnosed high-grade glioma. The FDA has granted CAN-2409 Fast Track designation for use in this setting in combination with standard of care surgery and chemoradiation. We intend to initiate a potential registrational Phase 3 trial in this indication in the first half of 2022.

In addition, we are advancing development of our HSV platform product candidates for different solid tumor indications. Our lead HSV product candidate, CAN-3110, is currently in an ongoing investigator-initiated Phase 1 clinical trial in our initial target indication of recurrent high-grade glioma, and we expect to report additional biomarker results in the fourth quarter of 2021. We are also designing novel candidates based on our HSV platform for the treatment of solid tumors.

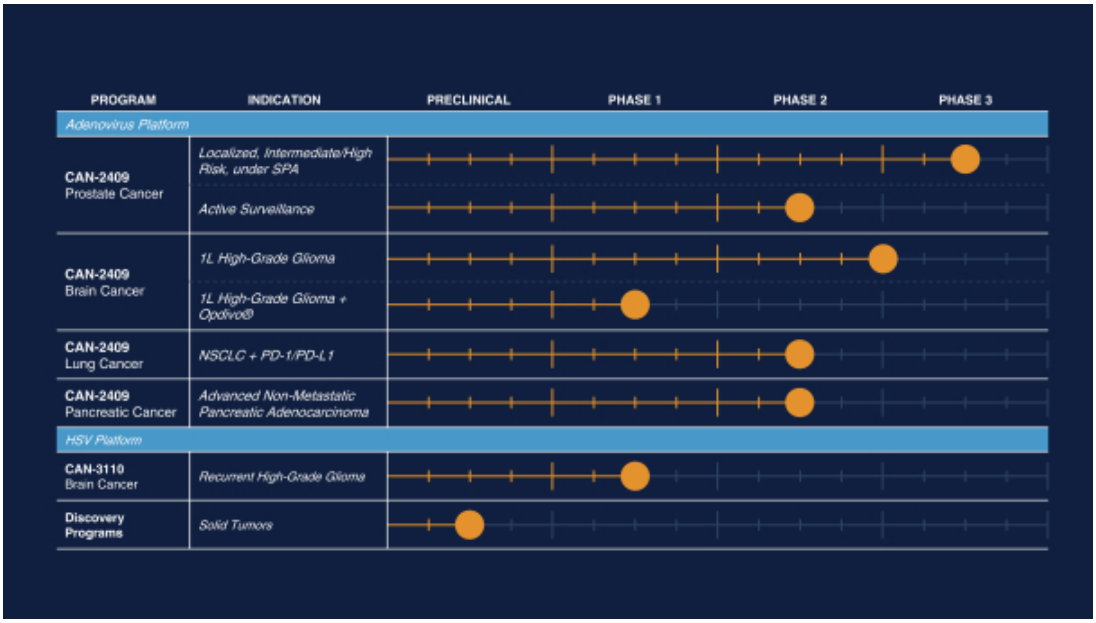
Our oncolytic viral immunotherapy approach utilizes intratumoral administration of genetically engineered viruses to selectively induce tumor cell death and elicit an innate and adaptive anti-tumor immune response. Local delivery enables us to achieve these effects while aiming to minimize systemic toxicity. The immune cells induced by these viral immunotherapies are believed to target patients' specific tumor antigens, potentially improving responses in immunologically "hot" tumors while at the same time infiltrating the tumor microenvironment, transforming non-inflamed "cold" tumors with limited immune response into "hot" tumors. Data from our clinical studies in patients with cancer have shown increases in the expression of immune checkpoints PD-1, PD-L1 and CTLA-4 following treatment with CAN-2409 supporting the evaluation of combinations with immune checkpoint inhibitors (ICI) such as anti-PD-(L)1 that, typically, are only efficacious in patients with immunologically "hot" tumors. While our product candidates are administered directly into the

tumor, we have observed systemic immune response in our preclinical studies and clinical trials that may indicate the potential of CAN-2409 and CAN-3110 to induce systemic immune response against distal, uninjected tumors, also known as an “abscopal” effect.

We believe oncolytic viral immunotherapy is among the most promising cancer treatment modalities today. Treatment with oncolytic viral immunotherapy has already been clinically validated through talimogene laherparepvec (Imlygic, Amgen), the first FDA-approved intratumoral oncolytic virus. Our goal is to further improve patient outcomes from oncolytic viral immunotherapies by selecting the optimal vector, specific transgenes and clinical indications for each tumor type while optimizing product candidate attributes, such as high-titer formulation, intratumoral administration, and storage conditions that could potentially lower logistical barriers for patients and clinicians.

We have an advanced pipeline comprised of six ongoing clinical trials based on our two lead product candidates. In addition, we own exclusive development and commercial rights for our product candidates in major territories including the United States, Europe and Asia.

Our pipeline is set forth below:



Corporate History and Our Team

Following the combination of our predecessor company, Advantagene, Inc. (Advantagene), with the HSV discovery platform assets acquired from Periphagen, Inc. (Periphagen), a company focused on engineering HSV as a gene therapy vector, we formally changed our name to Candel Therapeutics, Inc. in December 2020. Advantagene was built on a strong scientific foundation and developed CAN-2409 over years of research and development. In December 2019, Advantagene acquired substantially all the assets of Periphagen and in September 2020, licensed CAN-3110 from Mass General Brigham (formerly known as The Brigham and Women’s Hospital).

We were founded and are now led by a team of renowned drug developers, oncolytic viral immunotherapy experts, oncologists, immunologists and biotech business leaders. We are backed by a group of leading institutional life science investors, including PBM Capital, Northpond Ventures and Sands Capital Ventures.

Our Strengths

We believe our experience and capabilities in oncolytic viral immunotherapy will bring significant benefit to cancer patients who are underserved by the current standard of care, particularly in prostate and brain cancer. We believe our key strengths are:

- Deep clinical and development experience in innovative oncolytic viral immunotherapy.
- Two potentially registrational trials for our CAN-2409 programs in localized prostate and high-grade glioma, indications with significant unmet need supported by encouraging Phase 1/2 data.
- Two oncolytic viral immunotherapy platforms provide versatility and optionality to pursue a range of solid tumor indications.
- Attractive commercial profile and ownership of our programs.
- Commercial scale manufacturing strategy.

Our Strategy

Our goal is to develop best-in-class oncolytic viral immunotherapies to transform the lives of cancer patients. We plan to rapidly develop and commercialize our two lead product candidates, CAN-2409 and CAN-3110, for the treatment of a broad range of solid tumor indications, while continuing to build our pipeline through our discovery platform. Key elements of our strategy include the following:

- *Advance the late stage development of, and seek regulatory approval for, our lead product candidate, CAN-2409, in newly diagnosed, localized prostate cancer.*
- *Advance the development of, and seek regulatory approval for, CAN-2409 in both monotherapy and combination therapy for high-grade glioma.*
- *Advance the clinical development of CAN-3110, an oncolytic HSV with tumor-specific enhanced replication potency.*
- *Expand the development of CAN-2409 in other solid tumor indications, including non-small cell lung cancer (NSCLC) and pancreatic cancer.*
- *Leverage our HSV oncolytic viral immunotherapy platform to develop additional HSV product candidates.*
- *Complete our planned cGMP manufacturing facility.*
- *Develop strategic partnerships to maximize the value of our current and future product candidates.*

Risks Associated with Our Business

- We are a biopharmaceutical company with a limited operating history and have not generated any revenue to date from product sales.
- We have incurred significant operating losses since our inception and anticipate that we will incur continued losses for the foreseeable future.
- Even if we consummate this offering, we will need to raise substantial additional funding. If we are unable to raise capital when needed, we would be forced to delay, reduce or eliminate some of our product development programs or commercialization efforts.
- Our business is dependent on the success of our lead product candidate, CAN-2409, as well as CAN-3110 and any other product candidates that we advance into the clinic. All of our product candidates will require additional development before we may be able to seek regulatory approval for and launch a product commercially.
- Our preclinical studies and clinical trials may fail to demonstrate adequately the safety and efficacy of any of our product candidates, which would prevent or delay development, regulatory approval, and commercialization.
- Our product candidates are based on a novel approach to the treatment of cancer, which makes it difficult to predict the time and cost of product candidate development.

- Negative developments in the field of immuno-oncology and virus-based therapies could damage public perception of any of our product candidates and negatively affect our business.
- Difficulty in enrolling patients could delay or prevent clinical trials of our product candidates, and ultimately delay or prevent regulatory approval.
- We face substantial competition, which may result in others discovering, developing or commercializing product candidates before or more successfully than we do.
- Even if CAN-2409, CAN-3110 or any future product candidates receive regulatory approval, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense and limit how we manufacture and market our products.
- Achieving commercial scale for our manufacturing operations in our new facility or at third-party manufacturers may result in further delays or expenses, and we may not experience the anticipated operating efficiencies.
- If, in the future, we are unable to establish sales and marketing and patient support capabilities or enter into agreements with third parties to sell and market our current or future product candidates, we may not be successful in commercializing our current or future product candidates if and when they are approved, and we may not be able to generate any revenue.
- The COVID-19 pandemic, which began in late 2019 and has spread worldwide may affect our ability to complete our ongoing clinical trials and initiate and complete other preclinical studies, planned clinical trials or future clinical trials, disrupt regulatory activities, disrupt our manufacturing and supply chain or have other adverse effects on our business and operations. In addition, this pandemic has caused substantial disruption in the financial markets and may adversely impact economies worldwide, both of which could result in adverse effects on our business, operations and ability to raise capital.
- We have completed and may in the future complete related party transactions that were not and may not be conducted on an arm's length basis.
- Our rights to develop and commercialize any product candidates are subject and may in the future be subject, in part, to the terms and conditions of licenses granted to us by third parties. If we fail to comply with our obligations under our current or future intellectual property license agreements or otherwise experience disruptions to our business relationships with our current or any future licensors, we could lose intellectual property rights that are important to our business.

Corporate History and Information

We were incorporated under the laws of the State of Delaware in June 2003. Our principal executive office is located at 117 Kendrick St, Suite 450, Needham, Massachusetts 02494, and our telephone number is (617) 916-5445. Our website address is *www.candeltx.com.* We do not incorporate the information on or accessible through our website into this prospectus, and you should not consider any information on, or that can be accessed through, our website as part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- being permitted to only disclose two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- reduced disclosure about our executive compensation arrangements;

- not being required to hold advisory votes on executive compensation or to obtain stockholder approval of any golden parachute arrangements not previously approved; and
- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions until the fifth anniversary of our initial public offering or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (iv) the last day of the fiscal year in which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission, or SEC, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th. We may choose to take advantage of some but not all of these exemptions. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock. We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements under the JOBS Act. Subject to certain conditions, as an emerging growth company, we may rely on certain of these exemptions, including without limitation, providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act. We have elected to avail ourselves of this exemption and, therefore, while we are an emerging growth company we will not be subject to new or revised accounting standards at the same time that they become applicable to other public emerging growth companies that have not elected to avail themselves of this exemption.

We are also a ''smaller reporting company'' as defined in the Securities Exchange Act of 1934, or the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies until the fiscal year following the determination that our voting and non-voting common stock held by non-affiliates is more than $250 million measured on the last business day of our second fiscal quarter, or our annual revenues are more than $100 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is more than $700 million measured on the last business day of our second fiscal quarter.

THE OFFERING

Common stock offered by us	9,000,000 shares (or 10,350,000 shares if the underwriters exercise their option to purchase additional shares in full)
Common stock to be outstanding immediately after this offering	27,798,454 shares (or 29,148,454 shares if the underwriters exercise their option to purchase additional shares in full)
Underwriters' option to purchase additional shares	We have granted the underwriters an option exercisable for 30 days after the date of this prospectus, to purchase up to 1,350,000 additional shares from us.
Use of Proceeds	We estimate that the net proceeds from the sale of shares of our common stock in this offering will be approximately $63.2 million, or $73.2 million if the underwriters exercise in full their option to purchase additional shares, based on the initial public offering price of $8.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, to fund patient enrollment for our Phase 3 clinical trial of CAN-2409 in high-grade glioma through the first quarter of 2023; the development, construction and qualification of our manufacturing facility and the development of commercial manufacturing capabilities at third-party contract manufacturers through the first quarter of 2023; our Phase 3 clinical trial of CAN-2409 for newly diagnosed prostate cancer in patients who have an intermediate- or high-risk for progression; the development of CAN-2409 and CAN-3110 in other clinical trials currently in process or contemplated; the remaining proceeds for general corporate purposes, which may include the continued expansion of our HSV platform technology, hiring of additional personnel and consultants, capital expenditures and the costs of operating as a public company. See "Use of Proceeds" for additional information.
Risk Factors	You should carefully read the "Risk Factors" section of this prospectus for a discussion of factors that you should consider before deciding to invest in our common stock.
Directed Share Program	At our request, the underwriters have reserved up to 5% of the shares offered by this prospectus for sale at the initial public offering price in a directed share program for our directors, officers, employees and related persons. The number of shares of common stock available for sale to the general public in the offering will be reduced to the extent these persons purchase the directed shares in the program. Any directed shares not so purchased will be offered by the underwriters to the general public on the same terms as the other shares. Directed shares purchased in the program will not be subject to a lock-up restriction, with the exception of directed shares purchased by our directors and officers, which will be subject to a 180-day lock-up restriction. See "Underwriting" for additional information.

Nasdaq Global Market symbol "CADL"

The number of shares of our common stock to be outstanding after this offering is based on 18,798,454 shares of our common stock outstanding as of June 30, 2021 after giving effect to the conversion of our preferred stock into 7,066,565 shares of common stock immediately prior to completion of this offering and excludes:

- 4,079,006 shares of common stock issuable upon the exercise of stock options outstanding as of March 31, 2021 under our 2015 Stock Plan, or the 2015 Plan, at a weighted average exercise price of $1.60 per share;
- 78,307 shares of common stock reserved and available for future issuance under the 2015 Plan, as of March 31, 2021, which will cease to be available for issuance at the time that our 2021 Stock Option and Incentive Plan, or the 2021 Plan, becomes effective;
- 7,524,262 shares of common stock reserved and available for future issuance upon exercise of the outstanding warrants, as of June 30, 2021, at a weighted average exercise price of $6.69 per share;
- 2,054,000 shares of our common stock that will become available for future issuance under the 2021 Plan, which will become effective in connection with the completion of this offering; and
- 293,000 shares of common stock that will become available for future issuance under our 2021 Employee Stock Purchase Plan, or ESPP, which will become effective in connection with the completion of this offering.

Except as otherwise indicated, all information in this prospectus assumes or gives effect to:

- the conversion of all outstanding shares of our redeemable convertible preferred stock into an aggregate of 7,066,565 shares of our common stock immediately prior to the completion of this offering;
- no exercise of the outstanding options described above;
- no exercise of the outstanding warrants described above;
- no exercise by the underwriters of their option to purchase up to an additional 1,350,000 shares of our common stock in this offering;
- A one-for-2.4579 reverse split of our common stock and a proportionate adjustment in the ratio at which our preferred stock is convertible into our common stock, which will become effective prior to the completion of this offering; and
- the filing of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws, which will occur immediately prior to the completion of this offering.

SUMMARY CONSOLIDATED FINANCIAL DATA

You should read the following summary consolidated financial data together with our consolidated financial statements and the related notes appearing at the end of this prospectus and the "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of this prospectus. We have derived the statement of operations data for the years ended December 31, 2019 and 2020 and the consolidated balance sheet data as of December 31, 2020 from our audited consolidated financial statements appearing elsewhere in this prospectus. The summary unaudited condensed consolidated statement of operations data for the three months ended March 31, 2020 and 2021 and the summary unaudited condensed consolidated balance sheet data as of March 31, 2021 have been derived from our unaudited condensed consolidated financial statements included elsewhere in this prospectus, which have been prepared on the same basis as the audited financial statements. Our historical results are not necessarily indicative of results that should be expected in any future period.

(in thousands, except share and per share amounts)	YEAR ENDED DECEMBER 31,		THREE MONTHS ENDED MARCH 31,	
	2019	2020	2020	2021
			(unaudited)	
Research and development service revenue, related party	$ 125	$ 125	$ 31	$ 31
Operating expenses:				
Research and development	6,607	8,754	1,621	2,753
General and administrative	2,555	5,181	728	1,935
Total operating expenses	9,162	13,935	2,349	4,688
Loss from operations	(9,037)	(13,810)	(2,318)	(4,657)
Grant income	571	624	163	191
Interest, dividend and investment income (expense), net	1,070	111	(72)	(12)
Change in fair value of warrant liability	(844)	(4,605)	455	—
Net loss and new loss attributable to common stockholders	$ (8,240)	$ (17,680)	$ (1,772)	$ (4,478)
Net loss per share attributable to common stockholders, basic and diluted (1)	$ (0.71)	$ (1.52)	$ (0.15)	$ (0.38)
Weighted-average shares of common stock outstanding, basic and diluted (1)	11,533,718	11,615,208	11,614,335	11,647,786
Pro forma net loss per share attributable to common stockholders, basic and diluted		$ (0.95)		$ (0.24)
Pro forma weighted-average shares of common stock outstanding, basic and diluted		18,681,773		18,714,351

(1) See Note 16 to our audited consolidated financial statements appearing elsewhere in this prospectus for details on the calculation of basic and diluted net loss per share attributable to common stockholders.

(IN THOUSANDS)	AS OF MARCH 31, 2021 (unaudited) ACTUAL	PRO FORMA (1)	PRO FORMA AS ADJUSTED (2)
Consolidated Balance Sheet Data:			
Cash and cash equivalents	$ 29,152	$ 29,152	$ 92,484
Working capital (3)	23,973	23,973	88,070
Total assets	35,094	35,094	97,490
Total liabilities	13,531	13,531	12,766
Convertible preferred stock	49,060	—	—
Accumulated deficit	(48,649)	(48,649)	(48,649)
Total stockholders' (deficit) equity	(27,497)	21,563	84,723

(1) The pro forma consolidated balance sheet data gives effect to the automatic conversion of our convertible preferred stock into an aggregate of 7,066,565 shares of common stock upon the closing of this offering and assumes no exercise of any of our warrants outstanding upon the closing of this offering.

(2) The pro forma as adjusted consolidated balance sheet data gives effect to (i) the pro forma adjustments set forth in footnote (1) above and (ii) to our issuance and sale of 9,000,000 shares of our common stock in this offering at the initial public offering price of $8.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

(3) We define working capital as current assets less current liabilities.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this prospectus, including our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risks Related to Our Business, Financial Position and Capital Requirements

We are a biopharmaceutical company with a limited operating history and have not generated any revenue to date from product sales.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We were incorporated under the laws of the State of Delaware in June 2003. Since inception, we have focused substantially all of our efforts and financial resources on raising capital and developing our initial product candidates. To date, we have financed our operations primarily through the issuance and sale of our convertible preferred stock to outside investors in private equity financings. From our inception through June 30, 2021, we raised an aggregate of $66.1 million of gross proceeds from such transactions. As of March 31, 2021, our cash and cash equivalents and investments were $29.2 million. We have incurred net losses in each year since our inception, and we had an accumulated deficit of $48.6 million as of March 31, 2021. For the three months ended March 31, 2021 and for the years ended December 31, 2020 and December 31, 2019, we reported net losses of $4.5 million, $17.7 million and $8.2 million, respectively. We have no products approved for commercial sale and therefore have never generated any revenue from product sales, and we do not expect to do so in the foreseeable future. We have not obtained regulatory approvals for any of our product candidates, and even if our clinical development efforts result in positive data, our product candidates may not receive regulatory approval or be successfully introduced and marketed at prices that would permit us to operate profitably. We expect to continue to incur significant expenses and operating losses over the next several years and for the foreseeable future. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' deficit and working capital.

We have incurred significant operating losses since our inception and anticipate that we will incur continued losses for the foreseeable future.

Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect our research and development expenses to significantly increase in connection with the commencement and continuation of clinical trials of our product candidates. In addition, if we obtain marketing approval for our product candidates, we will incur significant sales, marketing and manufacturing expenses. Once we are a public company, we will incur additional costs associated with operating as a public company. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

The amount of our future losses is uncertain, and our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline. Our quarterly and annual operating results may fluctuate significantly in the future due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- our ability to successfully enroll and retain subjects for clinical trials, and any delays caused by difficulties in such efforts;

- our ability to obtain marketing approval for our product candidates, and the timing and scope of any such approvals we may receive;
- the changing and volatile U.S. and global economic environments, including as a result of the COVID-19 pandemic;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- the cost of manufacturing our product candidates, which may vary depending on the quantity of production, and the success of achieving commercial scale manufacturing operations in our new facility or at third-party manufacturers;
- our ability to attract, hire and retain qualified personnel;
- expenditures that we will or may incur to develop additional product candidates;
- the level of demand for our product candidates should they receive approval, which may vary significantly;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future therapeutics that compete with our product candidates; and
- future accounting pronouncements or changes in our accounting policies.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide.

We have no products approved for commercial sale and have not generated any revenue from product sales.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from our product candidates, and we do not expect to generate any revenue from the sale of products in the near future. We do not expect to generate significant revenue unless and until we obtain marketing approval of, and begin to sell, one or more of our product candidates. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- successfully complete our ongoing and planned preclinical studies and clinical trials for our oncolytic viral immunotherapy programs;
- timely file and receive acceptance of our Investigational New Drug applications, or INDs, in order to commence our planned clinical trials or future clinical trials;
- successfully enroll subjects in, and complete, clinical trials for our oncolytic viral immunology programs;
- implement measures to help minimize the risk of COVID-19 to our employees as well as patients enrolled in our trials;
- timely file NDAs and receive regulatory approvals for our product candidates from the FDA and comparable foreign regulatory authorities;
- initiate and successfully complete all safety studies required to obtain U.S. and foreign marketing approval for our product candidates;
- establish commercial manufacturing capabilities through build out and qualification of our planned facility or make arrangements with third-party manufacturers for clinical supply and commercial manufacturing;
- obtain and maintain patent and trade secret protection or regulatory exclusivity for our product candidates;
- launch commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- maintain a continued acceptable safety profile of the product candidates following approval;
- obtain and maintain acceptance of the product candidates, if and when approved, by patients, the medical community and third-party payors;
- position our products to effectively compete with other therapies;

- obtain and maintain favorable coverage and adequate reimbursement by third-party payors for our product candidates;
- enforce and defend intellectual property rights and claims with respect to our product candidates; and
- hire additional staff, including clinical, scientific and management personnel.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

Even if we consummate this offering, we will need to raise substantial additional funding. If we are unable to raise capital when needed, we would be forced to delay, reduce or eliminate some of our product development programs or commercialization efforts.

The development of pharmaceutical products is capital-intensive. We are currently advancing our product candidates through clinical development across a number of potential indications. We are currently conducting a Phase 3 clinical trial for CAN-2409 in newly diagnosed localized prostate cancer in intermediate and high-risk patients for which we expect to complete enrollment in the third quarter of 2021 and receive final data readout in 2024. Our second program using the candidate CAN-2409 is for the treatment of a type of brain cancer called high grade glioma. We intend to initiate a potential registrational Phase 3 trial in this indication in the first half of 2022. Consequently, we expect our expenses to significantly increase in connection with our ongoing activities, particularly as we continue our ongoing clinical trials or initiate future trials and pursue the research and development of, and seek marketing approval for, our product candidates. In addition, depending on the status of regulatory approval or, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. We may also need to raise additional funds sooner if we choose to pursue additional indications and/or geographies for our product candidates or otherwise expand more rapidly than we presently anticipate. Furthermore, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate certain of our research and development programs or future commercialization efforts, and may be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

We expect that the net proceeds from this offering, together with our existing cash and cash equivalents and investments will be sufficient to fund our operations through the first quarter of 2023. However, our future capital requirements will depend on and could increase significantly as a result of many factors, including:

- the scope, progress, results and costs of product discovery, preclinical and clinical development, laboratory testing and clinical trials for the development of CAN-2409, CAN-3110, or our other potential product candidates;
- the timing of, and the costs involved in, obtaining marketing approvals for CAN-2409 in newly diagnosed localized prostate cancer and high grade glioma as well as for CAN-3110 in our initial target indication of recurrent high-grade glioma and our other potential product candidates that we may develop;
- if approved, the costs of commercialization activities for CAN-2409 or CAN-3110 for any approved indications or any other product candidate that receives regulatory approval to the extent such costs are not the responsibility of a collaborator that we may contract with in the future, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- the potential additional expenses attributable to adjusting our development plans (including any supply related matters) to the COVID-19 pandemic;
- the scope, prioritization and number of our research and development programs;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to establish and maintain additional collaborations on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under any additional collaboration agreements we may enter into;

- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under future collaboration agreements, if any;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of securing manufacturing arrangements for commercial production;
- the emergence of competing oncolytic viral immunotherapies as well as immuno-oncology therapies in general and other adverse market developments;
- the costs of transitioning our manufacturing operations to our new facility;
- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory approvals to market our product candidates; and
- the ongoing impact of the COVID-19 pandemic, which may exacerbate the magnitude of the factors discussed above.

Identifying potential product candidates and conducting preclinical development testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. Disruptions in the financial markets in general, and more recently due to the COVID-19 pandemic, have made equity and debt financing more difficult to obtain, and may have a material adverse effect on our ability to meet our fundraising needs. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborators or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product candidate or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

Risks Related to Product Development

Our business is dependent on the success of our lead product candidate, CAN-2409, as well as CAN-3110 and any other product candidates that we advance into the clinic. All of our product candidates will require additional development before we may be able to seek regulatory approval for and launch a product commercially.

We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We expect that a substantial portion of our efforts and expenditures over the next several years will be devoted to our CAN-2409 program, which is currently our lead product candidate. We are currently conducting, as part of our most advanced CAN-2409 program, a Phase 3 clinical trial under an SPA for CAN-2409 in patients with newly diagnosed localized prostate cancer who have an intermediate or high-risk for progression. We expect to

complete enrollment for this trial in the third quarter of 2021 with a final data readout in 2024. We are also evaluating CAN-2409 in high-grade glioma and intend to initiate a potential registrational Phase 3 trial in this indication in the first half of 2022. Additionally, we have an ongoing investigator-initiated Phase 1 clinical trial for CAN-3110, our most advanced product candidate from our HSV platform, in our initial target indication of recurrent high-grade glioma and expect to report additional biomarker results in the fourth quarter of 2021. If CAN-2409 encounters safety or efficacy issues, development delays, regulatory issues or other problems, our development plans and business would be significantly harmed. We can provide no assurance that CAN-2409, CAN-3110 or any other product candidates we develop will receive regulatory approval or be successfully commercialized even if we receive regulatory approval. If we were required to discontinue development of CAN-2409 or CAN-3110, or if CAN-2409 or CAN-3110 do not receive regulatory approval or fail to achieve significant market acceptance, we would be delayed by many years in our ability to achieve profitability, if ever.

Furthermore, even if we obtain regulatory approval for CAN-2409, CAN-3110 or any other product candidates we develop, we will still need to develop a commercial infrastructure, build out our manufacturing capabilities or develop relationships with collaborators to commercialize, establish a commercially viable pricing structure and obtain coverage and adequate reimbursement from third-party payors, including government healthcare programs. If we, or any future collaborators, are unable to successfully commercialize CAN-2409, CAN-3110 or any other product candidates we develop, we may not be able to generate sufficient revenue to continue our business.

Our preclinical studies and clinical trials may fail to demonstrate adequately the safety and efficacy of any of our product candidates, which would prevent or delay development, regulatory approval, and commercialization.

Before obtaining regulatory approvals for the commercial sale of our product candidates, including CAN-2409, CAN-3110 or any other product candidates we develop, we must demonstrate the safety and efficacy of our product candidates for use in each target indication through lengthy, complex, and expensive preclinical studies and clinical trials. Failure can occur at any time during the preclinical study and clinical trial processes and there is a high risk of failure, so we may never succeed in developing marketable products. Any preclinical studies or clinical trials that we may conduct may not demonstrate the safety and efficacy necessary to obtain regulatory approval to market any of our product candidates. If the results of our ongoing or future preclinical studies and clinical trials are inconclusive with respect to the safety and efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for such product candidates. In some instances, there can be significant variability in safety or efficacy results between different preclinical studies and clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. While we are currently in Phase 3 clinical trials for CAN-2409 and are in early stages of clinical development for CAN-3110, it is likely, as is the case with many oncology therapies, that there may be side effects associated with their use. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Further, our product candidates have caused undesirable side effects in clinical trials related to on-target toxicity such as fever, chills and muscle aches and other flu-like symptoms that occurred across our trials. Patients recruited in our trials experienced the following grade 3 and grade 4 related side effects. In our prostate cancer Phase 2 clinical trial, one patient presented a grade 3 genitourinary toxicity, and one patient presented with a transient grade 3 ALT elevation without clinical significance. In our high-grade glioma Phase 1b/2 clinical trial, patients experienced the following adverse events: one patient presented with grade 4 hemiparesis and grade 3 worsening of speech impairment; one patient presented with grade 3 insomnia; one patient experienced grade 3 headache; one patient experienced grade 3 wound complications; one patient experienced grade 4 motor-neuropathy symptoms/signs; seven patients experienced grade 3 transient lymphopenia; and three patients experienced grade 3 AST/ALT alterations. In our NSCLC Phase 1 clinical trial, two patients experienced grade 3 dehydration with renal insufficiency, two patients presented grade 3 urinary retention and six patients were observed to have a grade 4 low lymphocyte count. In our

pancreatic cancer Phase 1 clinical trial, two patients displayed a grade 3 worsening of abdominal pain and one patient presented grade 3 dehydration with increased creatinine, three patients experienced grade 3 or 4 increased ALT/AST, three patients experienced grade 3 or 4 increased bilirubin, three patients experienced grade 3 or 4 increased lipase and two patients experienced grade 3 or 4 low lymphocyte count. If on-target toxicity is observed at unacceptable levels, or if our product candidates have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. In addition, our product candidates could cause undesirable side effects that we have not observed yet to date. Many compounds that initially showed promise in early stage testing for treating cancer have later been found to cause side effects that prevented further development of the compound. In addition to our ongoing clinical trials of CAN-2409 and CAN-3110, patients have been, and may continue to be, treated with CAN-2409 and/or CAN-3110 under an expanded access or "compassionate use" program. To the extent the experiences of patients being treated in this program are inconsistent with or less favorable than the results of our ongoing or planned company-sponsored trials with CAN-2409 and/or CAN-3110, it may negatively affect perceptions of CAN-2409 and/or CAN-3110, our other product candidates, or our business. In addition, the FDA or comparable foreign regulatory authorities may require us to obtain and submit additional clinical data due to these inconsistent or unfavorable results, which could delay clinical development or marketing approval of CAN-2409 and/or CAN-3110 or potentially our other product candidates.

Interim, top line and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to regulatory audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim, top line or preliminary data from our clinical trials. We may decide to conduct an interim analysis of the data after a certain number or percentage of patients have been enrolled, or after only a part of the full follow-up period but before completion of the trial. Similarly, we may report top line or preliminary results of primary and key secondary endpoints before the final trial results are completed. Preliminary, top line and interim data from our clinical trials may change as more patient data or analyses become available. Preliminary, top line or interim data from our clinical trials are not necessarily predictive of final results and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues, more patient data become available and we issue our final clinical trial report. These data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, preliminary, interim and top line data should be viewed with caution until the final data are available. Material adverse changes in the final data compared to the interim data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, topline, or preliminary data that we report differ from more complete results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain marketing authorization for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Results of earlier studies and trials of our product candidates may not be predictive of future trial results.

Success in preclinical studies and early clinical trials does not ensure that later clinical trials will be successful. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. As we commence new clinical trials and continue our ongoing clinical trials, issues may arise that could suspend or terminate such clinical trials. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in clinical trials, even after positive results in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made

in clinical trials, including previously unreported adverse events. Notwithstanding any potential promising results in earlier studies and trials, we cannot be certain that we will not face similar setbacks. In addition, the results of our preclinical animal studies, including our oncology mouse studies and animal studies, may not be predictive of the results of outcomes in human clinical trials. For example, our oncology product candidates that are in preclinical development may demonstrate different chemical and biological properties in patients than they do in laboratory animal studies or may interact with human biological systems in unforeseen or harmful ways.

Additionally, some of past, ongoing and planned clinical trials utilize and "open-label" study design. An "open-label" clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect, as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. Moreover, patients selected for early clinical studies often include the most severe sufferers and their symptoms may have improved notwithstanding the new treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge.

Our product candidates are based on a novel approach to the treatment of cancer, which makes it difficult to predict the time and cost of product candidate development and subsequently obtaining regulatory approval, if at all.

We have concentrated all of our research and development efforts on our CAN-2409 and CAN-3110 product candidates, and our future success depends on the successful development of these therapeutic approaches. In particular, CAN-2409 utilizes adenoviruses to activate the innate and adaptive immune system. To our knowledge, there are no FDA-approved products for the treatment of cancer that utilize the adenovirus.

We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. Few viral immunotherapies have been approved globally or by the FDA to date. While the first viral immunotherapy, talimogene laherparepvec (Imlygic, Amgen), has received FDA approval, regulatory agencies have reviewed relatively few viral immunotherapy product candidates such as CAN-2409 and CAN-3110. This may lengthen the regulatory review process, increase our development costs and delay or prevent commercialization of our product candidates. Further, any viral immunotherapies that are approved may be subject to extensive post-approval regulatory requirements, including requirements pertaining to manufacturing, distribution and promotion. We may need to devote significant time and resources to compliance with these requirements.

The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support licensure. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain licensure of the product candidates based on the completed clinical trials, as the FDA often adheres to the Advisory Committee's recommendations. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained.

In addition, our product candidates are live, gene-modified viruses for which the FDA, the EMA and other comparable foreign regulatory authorities and other public health authorities, such as the Centers of Disease Control and Prevention and hospitals involved in clinical studies, have established additional safety and contagion rules and procedures, which could establish additional hurdles for the development, manufacture or use of our vectors. These hurdles may lead to delays in the conduct of clinical trials or in obtaining regulatory approvals for further development, manufacturing or commercialization of our product candidates. We may also experience delays in transferring our process to commercial partners, which may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all.

Furthermore, there has been limited historical clinical trial experience for the development of products that utilize the adenovirus. Moreover, the design and conduct of our clinical trials differs from the design and conduct of previously conducted clinical trials in this area. In particular, regulatory authorities in the United States and in other

jurisdictions, including Europe, have not issued definitive guidance as to how to measure and demonstrate efficacy in newly diagnosed localized prostate cancer in intermediate- to high-risk patients in combination with the standard of care. As a result, there is substantial risk that the design or outcomes of our clinical trials will not be satisfactory to support marketing approval. For example, the endpoint in our Phase 3 clinical trial with CAN-2409 is a disease-free survival (DFS) endpoint with final results expected 24 months after last patient treated, which has not been utilized in prior trials and may not be accepted by regulators as a basis for approval despite the existence of the SPA. Even if this type of novel endpoint is accepted as a basis for approval in the United States, we cannot be certain that regulators outside of the United States will accept such endpoints or will not require us to conduct additional validation studies to support the suitability of such endpoints for approval in these jurisdictions.

We are developing, and in the future may develop, other product candidates, in combination with other therapies, which exposes us to additional risks related to any prodrugs or any agents used in combination with our product candidates.

Our CAN-2409 product candidate is being developed to be used in combination with the prodrug valacyclovir, which is a small molecule drug marketed for treatment of genital herpes. In the future, we may develop other product candidates to be used with one or more currently approved other therapies. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or comparable foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop any of our product candidates for use in combination with other drugs or for indications other than cancer. This could result in our own products being removed from the market or being less successful commercially.

If the FDA or comparable foreign regulatory authorities revoke their approval of these other drugs or revoke their approval of, or if safety, efficacy, manufacturing or supply issues arise with, the drugs we choose to evaluate in combination with any product candidate we develop, we may be unable to obtain approval.

We may also evaluate our future product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA or comparable foreign regulatory authorities. We will not be able to market any product candidate we develop in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval. In addition, unapproved therapies face the same risks described with respect to our product candidates currently in development and clinical trials, including the potential for serious adverse effects, delays in their clinical trials and lack of FDA approval.

Negative developments in the field of immuno-oncology and, in particular, oncolytic viral immunotherapy, could damage public perception of any of our product candidates and negatively affect our business.

The commercial success of adenovirus- or oHSV-based product candidates will depend in part on public acceptance of the use of immuno-oncology, and, in particular, oncolytic viral immunotherapy. Adverse events in clinical trials of CAN-2409, CAN-3110 or any other adenovirus- or oHSV-based product candidates which we may develop, or in clinical trials of others developing similar products and the resulting publicity, as well as any other negative developments in the field of immuno-oncology that may occur in the future, including in connection with competitor therapies, could result in a decrease in demand for any adenovirus- or oHSV-based product candidates that we may develop. These events could also result in the suspension, discontinuation, or clinical hold of or modification to our clinical trials. If public perception is influenced by claims that the use of oncolytic immunotherapies is unsafe, whether related to our therapies or those of our competitors, our product candidates may not be accepted by the general public or the medical community and potential clinical trial subjects may be discouraged from enrolling in our clinical trials. In addition, responses by national or state governments to negative public perception may result in new legislation or regulations that could limit our ability to develop or commercialize any product candidates, obtain or maintain regulatory approval or otherwise achieve profitability. More restrictive statutory regimes, government regulations or negative public opinion would have an adverse effect on our business, financial condition, prospects and results of operations and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop. As a result, we may not be able to continue or may be delayed in conducting our development programs.

Our product candidates consist of modified viruses. Adverse developments in clinical trials of other immunotherapy products based on viruses, like oncolytic viruses, may result in a disproportionately negative effect for our technologies as compared to other products in the field of infectious disease and immuno-oncology that are not based on viruses. Future negative developments in the biopharmaceutical industry could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our products. Any increased scrutiny could delay or increase the costs of obtaining marketing approval for our product candidates.

Difficulty in enrolling patients could delay or prevent clinical trials of our product candidates, and ultimately delay or prevent regulatory approval.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of completion of our clinical trials depends in part on the speed at which we can recruit patients to participate in testing our product candidates, and we may experience delays in our clinical trials if we encounter difficulties in enrollment. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or comparable foreign regulatory authorities, or as needed to provide appropriate statistical power for a given trial. In particular, because we are focused on patients with brain cancer for the development of CAN-2409 and CAN-3110 our ability to enroll eligible patients may be limited or enrollment may be slower than we anticipate due to the small eligible patient population. In addition, our ability to enroll patients may be significantly delayed by the evolving COVID-19 pandemic and we are unable to predict the full extent and scope of such delays at this point.

In addition to the potentially small target populations for our planned clinical trials, particularly in brain cancer, the eligibility criteria will further limit the pool of available trial participants as we will require that patients have specific characteristics, such as a certain severity or stage of disease progression, to include them in a trial. Additionally, the process of finding eligible patients may prove costly. We also may not be able to identify, recruit, and enroll a sufficient number of patients to complete our clinical trials because of the perceived risks and benefits of the product candidate under evaluation, the availability and efficacy of competing therapies and clinical trials, the proximity and availability of clinical trial sites for prospective patients, the availability of genetic sequencing information for patient tumors so that we can identify patients with the targeted genetic mutations, and the patient referral practices of physicians. If patients are unwilling to participate in our studies for any reason, the timeline for recruiting patients, conducting studies, and obtaining regulatory approval of potential products may be delayed.

The enrollment of patients further depends on many factors, including:

- the proximity of patients to clinical trial sites;
- patient referral practices of physicians;
- the design of the clinical trial, including the number of site visits and invasive assessments required;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents;
- reporting of the preliminary results of any of our clinical trials;
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before clinical trial completion; and
- factors we may not be able to control, such as the COVID-19 pandemic that may limit patient participation, hiring of principal investigators or staff or clinical site availability.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us because some patients who might have opted to enroll in our clinical trials may instead opt to enroll in a clinical trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Moreover, because certain of our product candidates represent a departure from more commonly used methods for cancer treatment and because certain of our product candidates have not been tested in humans before, potential

patients and their doctors may be inclined to use conventional therapies, such as chemotherapy, rather than enroll patients in any future clinical trial of our product candidates.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenue from any of these product candidates could be delayed or prevented.

Even if we receive marketing approval for our current or future product candidates, our current or future product candidates may not achieve broad market acceptance, which would limit the revenue that we generate from their sales.

The commercial success of our current or future product candidates, if approved by the FDA or other applicable regulatory authorities, will depend upon the awareness and acceptance of our current or future product candidates among the medical community, including physicians, patients and healthcare payors. Market acceptance of our current or future product candidates, if approved, will depend on a number of factors, including, among others:

- the efficacy of our current or future product candidates as demonstrated in clinical trials, and, if required by any applicable regulatory authority in connection with the approval for the applicable indications, to provide patients with incremental health benefits, as compared with other available medicines;
- limitations or warnings contained in the labeling approved for our current or future product candidates by the FDA or other applicable regulatory authorities;
- the prevalence and severity of adverse events associated with our product candidates or those products with which they may be co-administered in immuno-oncology and, in particular, oncolytic viral immunotherapies;
- the clinical indications for which our current or future product candidates are approved;
- availability of alternative treatments already approved or expected to be commercially launched in the near future;
- the potential and perceived advantages of our current or future product candidates over current treatment options or alternative treatments, including future alternative treatments;
- the willingness of the target patient populations to try new therapies or treatment methods and of physicians to prescribe these therapies or methods in immuno-oncology and, in particular, oncolytic viral immunotherapies;
- the need to dose such product candidates in combination with other therapeutic agents, and related costs;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments;
- pricing and cost effectiveness;
- the effectiveness of our sales and marketing strategies;
- our ability to increase awareness of our current or future product candidates;
- our ability to obtain sufficient third-party coverage or reimbursement;
- the ability or willingness of patients to pay out-of-pocket in the absence of third-party coverage; and
- potential product liability claims.

If our current or future product candidates are approved but do not achieve an adequate level of acceptance by patients, physicians and payors, we may not generate sufficient revenue from our current or future product candidates to become or remain profitable. Before granting reimbursement approval, healthcare payors may require us to demonstrate that our current or future product candidates, in addition to treating these target indications, also provide incremental health benefits to patients. Our efforts to educate the medical community, patient organizations and third-party payors about the benefits of our current or future product candidates may require significant resources and may never be successful.

We face substantial competition, which may result in others discovering, developing or commercializing product candidates before or more successfully than we do.

The development and commercialization of new product candidates is highly competitive. We face competition from major pharmaceutical, specialty pharmaceutical and biotechnology companies among others with respect to CAN-

2409 and CAN-3110 and will face similar competition with respect to any product candidates that we may seek to develop or commercialize in the future. We compete in pharmaceutical, biotechnology and other related markets that develop immune-oncology therapies for the treatment of cancer. There are other companies working to develop viral immunotherapies for the treatment of cancer including divisions of large pharmaceutical and biotechnology companies of various sizes. The large pharmaceutical and biotechnology companies that have commercialized and/or are developing immuno-oncology treatments for cancer include AstraZeneca, Bristol-Myers Squibb, Gilead Sciences, Merck, Novartis, Pfizer and Roche/Genentech.

Some of the products and therapies developed by our competitors are based on scientific approaches that are the same as or similar to our approach, including with respect to the use of viral immunotherapy with adenovirus and HSV. Other competitive products and therapies are based on entirely different approaches. We are aware that Oncorus, Replimune, Amgen, Immavir, Fergene and IconOVir, among others, are developing viral immunotherapies that may have utility for the treatment of indications that we are targeting. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Many of the companies we compete against or may compete against in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in concentration of even more resources among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, in establishing clinical trial sites and enrolling subjects for our clinical trials and in acquiring technologies complementary to, or necessary for, our programs.

We could see a reduction or elimination of our commercial opportunity if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, or are more convenient or are less expensive than any products that we or our collaborators may develop. Our competitors also may obtain FDA or foreign regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of all our product candidates, if approved, are likely to be their efficacy, safety, convenience and price, if required, the level of biosimilar or generic competition and the availability of reimbursement from government and other third-party payors.

Risks Related to Government Regulation and Commercialization of Our Product Candidates

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are not able to obtain, or experience delays in obtaining, required regulatory approvals, we will not be able to commercialize CAN-2409, CAN-3110 and future product candidates as expected, and our ability to generate revenue may be materially impaired.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. These regulatory requirements may require us to amend our clinical trial protocols, including to comply with the protocols of any applicable SPA we receive from the FDA; conduct additional preclinical studies or clinical trials that may require regulatory or independent institutional review board, or IRB, approval; or otherwise cause delays in obtaining approval or rejection of an application. Any delay in obtaining or failure to obtain required approvals could materially adversely affect our ability to generate revenue from the particular product candidate, which may materially harm our business, financial condition, results of operations, stock price and prospects.

Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. The number and types of preclinical studies and clinical trials that will be required for regulatory approval also varies depending on the product candidate, the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular product candidate. Approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, and there may be varying interpretations of data obtained from preclinical studies or clinical trials, any of which may cause delays or limitations in the approval or a decision not to approve an application. It is possible that CAN-2409, CAN-3110 and future product candidates will never obtain the appropriate regulatory approvals necessary for us to commence product sales.

If we experience delays in obtaining approval, if we fail to obtain regulatory approval of CAN-2409, CAN-3110 or any future product candidate or if the label for a product candidate does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate, the commercial prospects for such product candidate may be harmed and our ability to generate revenues from that product candidate may be materially impaired.

CAN-2409, CAN-3110 or future product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any. Serious adverse events or undesirable side effects caused by CAN-2409, CAN-3110 and future product candidates could cause us, IRBs, and other reviewing entities or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. For example, if concerns are raised regarding the safety of a new therapeutic as a result of undesirable side effects identified during clinical or preclinical testing, the FDA or comparable foreign regulatory authority may order us to cease further development, decline to approve the product candidate or issue a letter requesting additional data or information prior to making a final decision regarding whether or not to approve the product candidate. The FDA or comparable foreign regulatory authorities, or IRBs and other reviewing entities, may also require, or we may voluntarily develop, strategies for managing adverse events during clinical development, which could include restrictions on our enrollment criteria, the use of stopping criteria, adjustments to a study's design, or the monitoring of safety data by a data monitoring committee, among other strategies. For example, patients enrolled in our ongoing clinical trials of CAN-2409 and CAN-3110 have experienced mild to moderate adverse events, consisting mainly of flu-like symptoms and injection site reactions. In response to these adverse events, we have implemented prophylactic measures, including intravenous fluids, antiemetics and antipyretics. The FDA's or a comparable foreign regulatory authority's requests for additional data or information could also result in substantial delays in the approval of CAN-2409, CAN-3110 and future product candidates.

Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of a product candidate may only be uncovered when a significantly larger number of patients are exposed to the product candidate or when patients are exposed for a longer period of time.

Undesirable side effects caused by CAN-2409, CAN-3110 or any future product candidates could also result in denial of regulatory approval by the FDA or comparable foreign regulatory authorities for any or all targeted indications or the inclusion of unfavorable information in our product labeling, such as limitations on the indicated uses for which the products may be marketed or distributed, a label with significant safety warnings, including boxed warnings, contraindications, and precautions, a label without statements necessary or desirable for successful commercialization, or may result in requirements for costly post-marketing testing and surveillance, or other requirements, including REMS, to monitor the safety or efficacy of the products, and in turn prevent us from commercializing and generating revenues from the sale of CAN-2409, CAN-3110 and future product candidates. Any such limitations or restrictions could similarly impact any supplemental marketing approvals we may obtain for CAN-2409 and CAN-3110. Undesirable side effects may limit the potential market for any approved products or could result in restrictions on manufacturing processes, the discontinuation of the sales and marketing of the

product, or withdrawal of product approvals. We could also be sued and held liable for harm caused to patients, or become subject to fines, injunctions or the imposition of civil or criminal penalties.

If CAN-2409, CAN-3110 and future product candidates are associated with serious adverse events or undesirable side effects or have properties that are unexpected, we may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. The therapeutic-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may materially harm our business, financial condition, results of operations, stock price and prospects.

The FDA's agreement to a Special Protocol Assessment with respect to the study design of our Phase 3 clinical trial of CAN-2409 in newly diagnosed localized prostate cancer in intermediate and high risk patients does not guarantee any particular outcome from regulatory review, including ultimate approval, and may not lead to a successful review or approval process.

We have obtained agreement from the FDA on the design and size of our Phase 3 clinical trial of CAN-2409 in newly diagnosed localized prostate cancer in intermediate and high risk patients in combination with the standard of care through an SPA. The FDA's SPA process is designed to facilitate the FDA's review and approval of drugs and biologics by allowing the FDA to evaluate the proposed design and size of certain clinical or animal studies, including clinical trials that are intended to form the primary basis for determining a product candidate's efficacy. Upon specific request by a clinical trial sponsor, the FDA will evaluate the protocol and respond to a sponsor's questions regarding protocol design and scientific and regulatory requirements. The FDA aims to complete SPA reviews within 45 days of receipt of the request. The FDA ultimately assesses whether specific elements of the protocol design of the trial, such as entry criteria, dose selection, endpoints and/or planned analyses, are acceptable to support regulatory approval of the product with respect to the effectiveness of the indication studied. All exchanges between the FDA and the sponsor regarding an SPA must be clearly documented in an SPA letter or the minutes of a meeting between the sponsor and the FDA.

Although the FDA may agree to an SPA, an SPA agreement does not guarantee approval of a product. Even if the FDA agrees to the design, execution, and analysis proposed in protocols reviewed under the SPA process, the FDA may revoke or alter its agreement in certain circumstances. In particular, an SPA agreement is not binding on the FDA if public health concerns emerge that were unrecognized at the time of the SPA agreement, other new scientific concerns regarding product safety or efficacy arise, the sponsor company fails to comply with the agreed upon trial protocols, or the relevant data, assumptions or information provided by the sponsor in a request for the SPA change or are found to be false or omit relevant facts. While we have obtained an SPA agreement for our Phase 3 clinical trial, we have subsequently made minor amendments to the protocol and have not obtained an SPA amendment in connection with the amended protocol.

In addition, even after an SPA agreement is finalized, the SPA agreement may be modified, and such modification will be deemed binding on the FDA review division, except under the circumstances described above, if the FDA and the sponsor agree in writing to modify the protocol. Generally, such modification is intended to improve the study. The FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from any study that is the subject of the SPA agreement.

Moreover, if the FDA revokes or alters its agreement under the SPA, or interprets the data collected from the clinical trial differently than we do, the FDA may not deem the data sufficient to support an application for regulatory approval of CAN-2409 in prostate cancer.

We have obtained orphan drug designation for CAN-2409 for use in combination with an anti-herpectic prodrug for treatment of malignant brain tumors; however, we may be unable to maintain this designation or obtain orphan drug designation for our other product candidates, and we may not be able to realize the benefits of such designation, including potential marketing exclusivity of our product candidates, if approved.

As part of our business strategy, we sought and have received orphan drug designation for CAN-2409 for use in combination with an anti-herpectic prodrug for treatment of malignant brain tumors; however, we may not be able to maintain this status. We may also seek additional orphan drug designations for CAN-2409 and for certain of our

future product candidates, and we may be unsuccessful in obtaining such designations. Regulatory authorities in some jurisdictions, including the United States and other major markets, may designate drugs and biologics intended to treat conditions or diseases affecting relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as having a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers.

Similarly, in Europe, the European Commission grants orphan drug designation after receiving the opinion of the EMA Committee for Orphan Medicinal Products on an orphan drug designation application. Orphan drug designation is intended to promote the development of drugs that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than 5 in 10,000 persons in Europe and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for drugs intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in Europe would be sufficient to justify the necessary investment in developing the drug. In Europe, orphan drug designation entitles a party to a number of incentives, such as protocol assistance and scientific advice specifically for designated orphan medicines, and potential fee reductions depending on the status of the sponsor.

Generally, if a product candidate with an orphan drug designation receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or EMA from approving another marketing application for a product that constitutes the same drug treating the same indication for that marketing exclusivity period, except in limited circumstances. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug or biologic no longer meets the criteria for orphan drug designation or if the drug or biologic is sufficiently profitable such that market exclusivity is no longer justified. Orphan drug exclusivity may be revoked if any regulatory agency determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition.

Even though we have obtained orphan drug designation for CAN-2409 for use in combination with an anti-herpectic prodrug for treatment of malignant brain tumors, and even if we are able to obtain orphan drug exclusivity for a future product candidate, that exclusivity may not effectively protect the relevant product candidate from competition because different therapies can be approved for the same condition and the same therapies can be approved for different conditions but used off-label for the orphan disease. Even after an orphan drug is approved, the FDA may subsequently approve another product for the same condition if the FDA concludes that the latter product is not the same product or is clinically superior to the protected orphan drug because it is shown to be safer or more effective, or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the orphan indication for which it was designated. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. While we have obtained orphan drug designation for CAN-2409 for use in combination with an anti-herpectic prodrug for treatment of malignant brain tumors, we may not be able to maintain such designation; and while we may seek orphan drug designation for applicable indications for any future product candidates, we may never receive such designations. Even though we have received such designation for CAN-2409, and may receive further such designations in the future, there is no guarantee that we will enjoy the benefits of those designations.

A Fast Track designation by the FDA, even though granted for CAN-2409, or if received for any other future product candidates, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive marketing approval.

If a drug or biologic is intended for the treatment of a serious or life-threatening condition and the product demonstrates the potential to address unmet medical needs for this condition, the product sponsor may apply for FDA Fast Track designation for a particular indication. We have been granted Fast Track designation for the use of CAN-2409 for the treatment of localized, primary prostate cancer in combination with radiation therapy to improve the local control rate, as well as for CAN-2409 in combination with standard of care surgery and chemoradiation to improve survival in adults with newly diagnosed high grade glioma decrease recurrence and improve disease-free survival and may seek Fast Track designation for CAN-3110 or certain of our future product candidates. However, there is no assurance that the FDA will grant this status to CAN-3110 or any of our proposed product candidates. Marketing applications filed by sponsors of products in Fast Track development may qualify for priority review under the policies and procedures offered by the FDA, but the Fast Track designation does not assure any such qualification or ultimate marketing approval by the FDA. The FDA has broad discretion whether or not to grant Fast Track designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even though we have received Fast Track designation for CAN-2409 or if we do receive Fast Track designation for CAN-3110 or any other of our future product candidates, we may not experience a faster development process, review or approval compared to conventional FDA procedures, and receiving a Fast Track designation does not provide assurance of ultimate FDA approval. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. In addition, the FDA may withdraw any Fast Track designation at any time.

A Breakthrough Therapy designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek Breakthrough Therapy designation for some or all of our future product candidates. A Breakthrough Therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Sponsors of product candidates that have been designated as Breakthrough Therapies are eligible to receive more intensive FDA guidance on developing an efficient drug development program, an organizational commitment involving senior managers, and eligibility for rolling review and priority review. Drugs and biologics designated as Breakthrough Therapies by the FDA may also be eligible for other expedited approval programs, including accelerated approval.

Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to product candidates developed and considered for approval that have not received Breakthrough Designation and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as Breakthrough Therapies, the FDA may later decide that the product no longer meets the conditions for qualification. Thus, even though we may seek Breakthrough Therapy designation for CAN-2409, CAN-3110 or some or all of our future product candidates for the treatment of various cancers, there can be no assurance that we will receive breakthrough therapy designation.

Accelerated approval by the FDA, even if granted for certain of our current or future product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek approval of certain of our current or future product candidates using the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition, generally provides a meaningful advantage over available therapies, and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. As a condition of approval, the FDA may require that a sponsor of a product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. These confirmatory trials must be completed with due diligence by the sponsor. In addition, the FDA currently

requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Even if we do receive accelerated approval, we may not experience a faster development or regulatory review or approval process, and receiving accelerated approval does not provide assurance of ultimate full FDA approval.

Even if our development efforts are successful, we may not obtain regulatory approval of CAN-2409, CAN-3110 or any future product candidates in the United States or other jurisdictions, which would prevent us from commercializing CAN-2409, CAN-3110 and future product candidates. Even if we obtain regulatory approval for CAN-2409, CAN-3110 and future product candidates, any such approval may be subject to limitations, including with respect to the approved indications or patient populations, which could impair our ability to successfully commercialize CAN-2409, CAN-3110 or any future product candidates.

We are not permitted to market or promote or sell CAN-2409, CAN-3110 or any future product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy for that indication. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities and clinical trial sites by, the regulatory authorities. If we do not receive approval from the FDA and comparable foreign regulatory authorities for any of CAN-2409, CAN-3110 and future product candidates, we will not be able to commercialize such product candidates in the United States or in other jurisdictions. If significant delays in obtaining approval for and commercializing CAN-2409, CAN-3110 and future product candidates occur in any jurisdictions, our business, financial condition, results of operations, stock price and prospects will be materially harmed. Even if CAN-2409, CAN-3110 and future product candidates are approved, they may:

- be subject to limitations on the indicated uses or patient populations for which they may be marketed, distribution restrictions, or other conditions of approval;
- not be approved with label statements necessary or desirable for successful commercialization; or
- contain requirements for costly post-market testing and surveillance, or other requirements, including the submission of a Risk Evaluation and Mitigation Strategy, or REMS, to monitor the safety or efficacy of the products.

We have not previously submitted a Biologics License Application, or BLA, to the FDA, or a similar marketing application to comparable foreign regulatory authorities, for CAN-2409, CAN-3110 or any product candidate, and we can provide no assurance that we will ultimately be successful in obtaining regulatory approval for claims that are necessary or desirable for successful marketing, if at all.

Changes in product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates are developed through preclinical studies to later-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Any of these changes could cause CAN-2409, CAN-3110 or any future product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Changes in third-party manufacturers and manufacturing processes may also require additional testing, or notification to, or approval by the FDA or a comparable foreign regulatory authority. Such changes could be further delayed due to development of commercial scale manufacturing operations in our new facility or at third-party manufacturers. This could delay completion of clinical trials, require the conduct of bridging clinical trials or studies, require the repetition of one or more clinical trials, increase clinical trial costs, delay approval of CAN-2409, CAN-3110 and future product candidates and jeopardize our ability to commence product sales and generate revenue.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as

a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products while local, national and international conditions warrant. On March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities and provided guidance regarding the conduct of clinical trials, which the FDA continues to update. As of June 23, 2020, the FDA noted it was continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals and conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. On July 16, 2020, the FDA noted that it is continuing to expedite oncology product development with its staff teleworking full-time. However, the FDA may not be able to continue its current pace and approval timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required, inparticular due to the COVID-19 pandemic and related travel restrictions. As of July 2020, utilizing a rating system to assist in determining when and where it is safest to conduct such inspections based on data about the virus' trajectory in a given state and locality and the rules and guidelines that are put in place by state and local governments, the FDA is either continuing to, on a case-by-case basis, conduct only mission critical inspections, or, where possible to do so safely, resuming prioritized domestic inspections, which generally include pre-approval inspections. Foreign pre-approval inspections that are not deemed mission-critical remain postponed, while those deemed mission-critical will be considered for inspection on a case-by-case basis. The FDA will use similar data to inform resumption of prioritized operations abroad as it becomes feasible and advisable to do so. The FDA may not be able to maintain this pace and delays or setbacks are possible in the future. Should the FDA determine that an inspection is necessary for approval, and an inspection cannot be completed during the review cycle due to restrictions on travel, the FDA has stated that it generally intends to issue a complete response letter. Further, if there is inadequate information to make a determination on the acceptability of a facility, the FDA may defer action on the application until an inspection can be completed. In 2020, several companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. If a prolonged government shutdown or other disruption occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Future shutdowns or other disruptions could also affect other government agencies such as the SEC, which may also impact our business by delaying review of our public filings, to the extent such review is necessary, and our ability to access the public markets.

Even if CAN-2409, CAN-3110 or any future product candidates receive regulatory approval, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense and limit how we manufacture and market our products.

Any product candidate for which we may obtain marketing approval will be subject to extensive and ongoing requirements of and review by the FDA and comparable foreign regulatory authorities, including requirements related to the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising, marketing, and promotional activities for such product. These requirements further include submissions of safety and other post-marketing information, including manufacturing deviations and reports, registration and listing requirements, the payment of annual fees, continued compliance with current good manufacturing practice, or cGMP, requirements relating to manufacturing, quality

control, quality assurance, and corresponding maintenance of records and documents, and good clinical practices, or GCPs, for any clinical trials that we conduct post-approval.

The FDA and comparable foreign regulatory authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of CAN-2409, CAN-3110 and future product candidates, they may withdraw approval, issue public safety alerts, require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on a product's indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. Any such restrictions could limit sales of the product.

We and any of our suppliers or collaborators, including our contract manufacturers, could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs and other FDA regulatory requirements. Application holders must further notify the FDA, and depending on the nature of the change, obtain FDA pre-approval for product and manufacturing changes.

In addition, later discovery of previously unknown adverse events or that the product is less effective than previously thought or other problems with any products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements both before and after approval, may yield various negative results, including:

- restrictions on manufacturing, distribution, or marketing of such products;
- restrictions on the labeling, including required additional warnings, such as boxed warnings, contraindications, precautions, and restrictions on the approved indication or use;
- manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance requiring remediation;
- modifications to promotional pieces;
- issuance of corrective information;
- requirements to conduct post-marketing studies or other clinical trials;
- clinical holds or termination of clinical trials;
- requirements to establish or modify a REMS or similar strategy;
- changes to the way the product is administered to patients;
- liability for harm caused to patients or subjects;
- reputational harm;
- the product becoming less competitive;
- warning or untitled letters;
- suspension of marketing or withdrawal of the products from the market;
- regulatory authority issuance of safety alerts, Dear Healthcare Provider letters, press releases, or other communications containing warnings or other safety information about the product;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recalls of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure or detention;
- FDA debarment, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from federal healthcare programs, consent decrees, or corporate integrity agreements; or
- injunctions or the imposition of civil, criminal or administrative penalties, including imprisonment.

Any of these events could prevent us from achieving or maintaining market acceptance of any particular product or could substantially increase the costs and expenses of commercializing such product, which in turn could delay or prevent us from generating significant revenues from its marketing and sale. Any of these events could further have

other material and adverse effects on our operations and business and could adversely impact our business, financial condition, results of operations, stock price and prospects.

Further, the FDA's policies or those of comparable foreign regulatory authorities may change and could impose extensive and ongoing regulatory requirements and obligations on any product candidate for which we obtain marketing approval. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and be subject to regulatory enforcement action, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Regulatory approval by the FDA or comparable foreign regulatory authorities is limited to those specific indications and conditions for which approval has been granted, and we may be subject to substantial fines, criminal penalties, injunctions or other enforcement actions if we are determined to be promoting the use of our products for unapproved or "off-label" uses, or in a manner inconsistent with the approved labeling, resulting in damage to our reputation and business.

We must comply with requirements concerning advertising and promotion for any product candidates for which we obtain marketing approval. Promotional communications with respect to therapeutics are subject to a variety of legal and regulatory restrictions and continuing review by the FDA, Department of Justice, Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress and the public. When the FDA or comparable foreign regulatory authorities issue regulatory approval for a product candidate, the regulatory approval is limited to those specific uses and indications for which a product is approved. If we are not able to obtain FDA approval for desired uses or indications for CAN-2409, CAN-3110 and future product candidates, we may not market or promote them for those indications and uses, referred to as off-label uses, and our business, financial condition, results of operations, stock price and prospects will be materially harmed. We also must sufficiently substantiate any claims that we make for any products, including claims comparing those products to other companies' products, and must abide by the FDA's strict requirements regarding the content of promotion and advertising.

Physicians may choose to prescribe products for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities. Regulatory authorities in the United States generally do not restrict or regulate the behavior of physicians in their choice of treatment within the practice of medicine. Regulatory authorities do, however, restrict communications by biopharmaceutical companies concerning off-label use.

If we are found to have impermissibly promoted any of CAN-2409, CAN-3110 and future product candidates, we may become subject to significant liability and government fines. The FDA and other agencies actively enforce the laws and regulations regarding product promotion, particularly those prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted a product may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. In the United States, engaging in the impermissible promotion of any products, following approval, for off-label uses can also subject us to false claims and other litigation under federal and state statutes. These include fraud and abuse and consumer protection laws, which can lead to civil and criminal penalties and fines, agreements with governmental authorities that materially restrict the manner in which we promote or distribute therapeutic products and conduct our business. These restrictions could include corporate integrity agreements, suspension or exclusion from participation in federal and state healthcare programs, and suspension and debarment from government contracts and refusal of orders under existing government contracts. These False Claims Act lawsuits against manufacturers of drugs and biologics have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements pertaining to certain sales practices and promoting off-label uses. In addition, False Claims Act lawsuits may expose manufacturers to follow-on claims by private payers based on fraudulent marketing practices. This growth in litigation has increased the risk that a biopharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, as well as criminal and civil penalties, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid, or other federal and state healthcare programs. If we do not lawfully promote our approved products, if any, we may

become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

In the United States, the promotion of biopharmaceutical products is subject to additional FDA requirements and restrictions on promotional statements. If, after CAN-2409, CAN-3110 or any future product candidates obtains marketing approval, the FDA determines that our promotional activities violate its regulations and policies pertaining to product promotion, it could request that we modify our promotional materials or subject us to regulatory or other enforcement actions, including issuance of warning letters or untitled letters, suspension or withdrawal of an approved product from the market, requests for recalls, payment of civil fines, disgorgement of money, imposition of operating restrictions, injunctions or criminal prosecution, and other enforcement actions. Similarly, industry codes in foreign jurisdictions may prohibit companies from engaging in certain promotional activities, and regulatory agencies in various countries may enforce violations of such codes with civil penalties. If we become subject to regulatory and enforcement actions, our business, financial condition, results of operations, stock price and prospects will be materially harmed.

We may not be able to file INDs or IND amendments to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA or a comparable foreign regulatory may not permit us to proceed.

The FDA or comparable foreign regulatory authorities may require us to file separate INDs for additional clinical trials we plan to conduct with our current lead product candidates, CAN-2409 and CAN-3110. We may not be able to file any additional INDs required for our current product candidates and any future product candidates on the timelines we expect. For example, we may experience manufacturing delays or other delays with IND-enabling studies, including due to the impact of the COVID-19 pandemic on suppliers, study sites or third-party contractors and vendors on whom we depend. We may also experience delays if we are unable to access earlier data from inactive or withdrawn INDs. Moreover, we cannot be sure that submission of an IND will result in the FDA or comparable foreign regulatory authorities allowing further clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, we cannot guarantee that such regulatory authorities will not change their requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or to a new IND. Any failure to file INDs on the expected timelines to obtain regulatory approvals for our trials may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all. There are similar risks related to the review and authorization of our protocols and amendments by comparable foreign regulatory authorities.

If approved, our investigational products regulated as biologics may face competition from biosimilars approved through an abbreviated regulatory pathway.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biologic products that are biosimilar to or interchangeable with an FDA-licensed reference biologic product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of the other company's product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty.

We believe that any of our product candidates approved as a biologic product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our investigational medicines to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once licensed, will be substituted for any one of our reference products in

a way that is similar to traditional generic substitution for non-biologic products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

If competitors are able to obtain marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences.

The size of the potential market for our product candidates is difficult to estimate and, if any of our assumptions are inaccurate, the actual markets for our product candidates may be smaller than our estimates.

Our current and future target patient populations are based on our beliefs and estimates regarding the incidence or prevalence of certain types of the indications that may be addressable by our product candidates, which is derived from a variety of sources, including scientific literature and surveys of clinics. Our projections may prove to be incorrect and the number of potential patients may turn out to be lower than expected. The total addressable market opportunity for our product candidates will ultimately depend upon a number of factors including the diagnosis and treatment criteria included in the final label, if approved for sale in specified indications, acceptance by the medical community, patient access, the success of competing therapies and product pricing and reimbursement. Further, the market opportunity for viral immunotherapies is hard to estimate given that it is an emerging field with few globally or FDA-approved therapies, none of which have yet to enjoy broad market acceptance. Even if we obtain significant market share for our product candidates, because the potential target populations could be small, we may never achieve profitability without obtaining regulatory approval for additional indications.

Healthcare reform measures may have a material adverse effect on our business and results of operations.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our current or future product candidates or any future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell a product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements, (ii) additions or modifications to product labeling, (iii) the recall or discontinuation of our products or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. More recently, however, on January 28, 2021, President Biden issued a new Executive Order which directs federal agencies to reconsider rules and other policies that limit Americans' access to healthcare and to consider actions that will protect and strengthen that access.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The ACA, among other things, subjects biological products to potential competition by lower-cost biosimilars, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (increased pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Various portions of the ACA are currently undergoing legal and constitutional challenges in the Fifth Circuit Court and the United States Supreme Court; the Trump Administration has issued various Executive Orders which eliminated cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices; and Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what affect further changes to the ACA would have on our business.

In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, and, due to subsequent legislative amendments, will remain in effect through 2030 unless additional Congressional action is taken. These Medicare sequester reductions were suspended from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic. The American Taxpayer Relief Act of 2012 among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There has been increasing legislative and enforcement interest in the U.S. with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposal for fiscal year 2021 contains further drug price control measures that could be enacted during the budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low income patients. Additionally, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of product candidates paid by consumers. The HHS has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. For example, in May 2019, the Centers for Medicare and Medicaid Services, or CMS, issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Further, the Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. Additionally, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. As a result, the FDA released a final rule on September 24, 2020, effective November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. On November 20, 2020, the CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. Any new laws or regulations that result in additional reductions in Medicare and other healthcare funding could have a material adverse effect on customers for our products, if approved, and, accordingly, on our results of operations.

Additionally, on October 1, 2020, the FDA issued a final rule allowing for the importation of certain prescription drugs from Canada. FDA also issued a final guidance document outlining a pathway for manufacturers to obtain an additional National Drug Code, or NDC, for an FDA-approved drug that was originally intended to be marketed in a

foreign country and that was authorized for sale in that foreign country. The regulatory and market implications of the final rule and guidance are unknown at this time, but legislation, regulations or policies allowing the reimportation of drugs, if enacted and implemented, could decrease the price we receive for our products and adversely affect our future revenues and prospects for profitability.

Further, on May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new product candidates that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its product candidates available to eligible patients as a result of the Right to Try Act.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our current or future product candidates or additional pricing pressures.

Our revenue prospects could be affected by changes in healthcare spending and policy in the U.S. and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. It is highly possible that additional governmental action is taken to address the COVID-19 pandemic. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future, including repeal, replacement or significant revisions to the ACA. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our current or future product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

If, in the future, we are unable to establish sales and marketing and patient support capabilities or enter into agreements with third parties to sell and market our current or future product candidates, we may not be successful in commercializing our current or future product candidates if and when they are approved, and we may not be able to generate any revenue.

We do not currently have a sales or marketing infrastructure and have limited experience in the sales, marketing, patient support or distribution of products. To achieve commercial success for any approved product candidate for which we retain sales and marketing responsibilities, we must build our sales, marketing, patient support, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. In the future, we may choose to build a focused sales and marketing infrastructure to sell, or participate in sales activities with our collaborators for, some of our current or future product candidates if and when they are approved.

There are risks involved with both establishing our own sales and marketing and patient support capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any drug launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our current or future product candidates on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to use any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing, patient support and distribution services, our drug revenues or the profitability of these drug revenues to us are likely to be lower than if we were to market and sell any current or future product candidates that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our current or future product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our current or future product candidates effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our current or future product candidates. Further, our business, results of operations, financial condition and prospects will be materially adversely affected.

If any product candidate for which we receive regulatory approval does not achieve broad market acceptance among physicians, patients, healthcare payors, and the medical community, the revenues that we generate from its sales will be limited.

Even if our product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors, and others in the medical community. Commercial success also will depend, in large part, on the coverage and reimbursement of our product candidates by third-party payors, including private insurance providers and government payors. The degree of market acceptance of any approved product would depend on a number of factors, including:

- the efficacy, safety and tolerability as demonstrated in clinical trials;
- the timing of market introduction of such product candidate as well as competitive products;
- the clinical indications for which the product is approved;
- acceptance by physicians, major operators of cancer or neurology clinics and patients of the product as a safe, tolerable and effective treatment;
- the potential and perceived advantages of the product candidate over alternative treatments;
- the safety and tolerability of the product candidate in a broader patient group;

- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement by third party payors and government authorities;
- changes in regulatory requirements by government authorities for the product candidate;
- relative convenience and ease of administration;
- the prevalence and severity of side effects and adverse events;
- the effectiveness of our sales and marketing efforts; and
- favorable or unfavorable publicity relating to the product or relating to the Company.

Our ability to successfully launch and secure market acceptance of our late-stage pipeline candidate, CAN-2409 (if approved), may be impacted by the evolving COVID-19 pandemic, although we are currently unable to predict or quantify any such potential impact with any degree of certainty. If the spread of COVID-19 and the social distancing measures taken by various governments continue, any commercial launch we may undertake may be hindered by various factors, including challenges in hiring the employees necessary to support commercialization; delays in demand due to impacts on the healthcare system and overall economy; delays in coverage decisions from Medicare and third-party payors; restrictions on our personal interactions with physicians, hospitals, payors, and other customers; interruptions or delays in our commercial supply chain; and increases in the number of uninsured or underinsured patients.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate sufficient revenue from these products and we may not become profitable, which would have a material adverse effect on our business.

If we fail to develop additional product candidates, our commercial opportunity could be limited.

We expect initially to develop our lead product candidates, CAN-2409 and CAN-3110. A key part of our strategy, however, is to pursue clinical development of additional product candidates. Developing, obtaining marketing approval for, and commercializing additional product candidates will require substantial additional funding beyond the net proceeds of this offering and will be subject to the risks of failure inherent in medical product development. We cannot assure you that we will be able to successfully advance any of these additional product candidates through the development process.

Even if we obtain approval from the FDA or comparable foreign regulatory authorities to market additional product candidates for the treatment of solid tumors, we cannot assure you that any such product candidates will be successfully commercialized, widely accepted in the marketplace, or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize additional product candidates our commercial opportunity may be limited and our business, financial condition, results of operations, stock price and prospects may be materially harmed.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Although we do not currently have any drugs on the market, if we begin commercializing our current or future product candidates, we will be subject to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments in which we conduct our business. Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any current or future product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our current or future product candidates for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order

- or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other hand. The term remuneration has been interpreted broadly to include anything of value. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. On November 20, 2020, the Office of Inspector General, or OIG, finalized further modifications to the federal Anti-Kickback Statute. Under the final rules, OIG added safe harbor protections under the Anti-Kickback Statute for certain coordinated care and value-based arrangements among clinicians, providers, and others. This rule (with exceptions) became effective January 19, 2021. We continue to evaluate what effect, if any, this rule will have on our business;
- the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties. Government enforcement agencies and private whistleblowers have investigated pharmaceutical companies for or asserted liability under the False Claims Act for a variety of alleged promotional and marketing activities, such as providing free products to customers with the expectation that the customers would bill federal programs for the products; providing consulting fees and other benefits to physicians to induce them to prescribe products; engaging in promotion for “off-label” uses; and submitting inflated best price information to the Medicaid Rebate Program. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false of fraudulent claim for purposes of the False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal physician payment transparency requirements, sometimes referred to as the “Sunshine Act” under the ACA require manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’s Health Insurance Program to report to the Department of Health and Human Services information related to physician payments and other transfers of value and the ownership and investment interests of such physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which also imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and some state laws require pharmaceutical

companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge and may not comply under one or more of such laws, regulations and guidance. Law enforcement authorities are increasingly focused on enforcing fraud and abuse laws, and it is possible that some of our practices may be challenged under these laws. Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations, including anticipated activities to be conducted by our sales team, were to be found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, any of which could adversely affect our ability to operate our business and our financial results.

We may face potential liability if we obtain identifiable patient health information from clinical trials sponsored by us.

Most healthcare providers, including certain research institutions from which we may obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by the HITECH. We are not currently classified as a covered entity or business associate under HIPAA and thus are not directly subject to its requirements or penalties. However, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. In addition, in the future, we may maintain sensitive personally identifiable information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations, and directly from individuals (or their healthcare providers) who may enroll in patient assistance programs if we choose to implement such programs. As such, we may be subject to state laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA.

The EU General Data Protection Regulation, or GDPR, also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers. The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR is a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. Further, the United Kingdom's decision to leave the European Union, referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear how data transfers to and from the United Kingdom will be regulated now that the United Kingdom has left the European Union.

In addition, California recently enacted and has proposed companion regulations to the California Consumer Privacy Act, or CCPA, which went into effect January 1, 2020. The CCPA creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide certain disclosures to

consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. As of March 28, 2020, the California State Attorney General has proposed varying versions of companion draft regulations which are not yet finalized. Despite the delay in adopting regulations, the California State Attorney General commenced enforcement actions against violators on July 1, 2020. While there are currently exceptions for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact our business activities. On August 14, 2020, implementing regulations were finalized and became effective as of that date. While clinical trial data and information governed by HIPAA are currently exempt from the current version of the CCPA, other personal information may be applicable and possible changes to the CCPA may broaden its scope. We continue to monitor the impact the CCPA may have on our business activities.

Furthermore, certain health privacy laws, data breach notification laws, consumer protection laws and genetic testing laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our collection, use and dissemination of individuals' health information. Patients about whom we or our collaborators may obtain health information, as well as the providers who may share this information with us, may have statutory or contractual rights that limit our ability to use and disclose the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

If we or third-party contract research organizations, or CROs, or other contractors or consultants fail to comply with applicable federal, state/provincial or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or our contractors' ability to develop and commercialize our therapeutic candidates and could harm or prevent sales of any affected therapeutics that we are able to commercialize, or could substantially increase the costs and expenses of developing, commercializing and marketing our therapeutics. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business. Increasing use of social media could give rise to liability, breaches of data security or reputational damage.

Additionally, we are subject to other state and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

Risks Related to Employee Matters, Managing Growth and General Business Operations

The COVID-19 pandemic, which began in late 2019 and has spread worldwide, may affect our ability to complete our ongoing clinical trials and initiate and complete other preclinical studies, planned clinical trials or future clinical trials, disrupt regulatory activities, disrupt our manufacturing and supply chain or have other adverse effects on our business and operations. In addition, this pandemic has caused substantial disruption in the financial markets and may adversely impact economies worldwide, both of which could result in adverse effects on our business, operations and ability to raise capital.

The COVID-19 pandemic, which began in December 2019 and has spread worldwide, has caused many governments to implement measures to slow the spread of COVID-19 through quarantines, travel restrictions, heightened border scrutiny and other measures. The COVID-19 pandemic and government measures taken in response have also had a significant impact, both directly and indirectly, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. The future progression of the COVID-19 pandemic and its effects on our business and operations are uncertain.

The extent to which COVID-19 impacts our operations or those of the third parties on which we rely will depend on many factors, which are highly uncertain and cannot be predicted with confidence, including the duration of the pandemic, additional or modified government actions, new information that will emerge concerning the severity and impact of COVID-19, and the actions to contain the COVID-19 pandemic or address its impact in the short and long term. Additionally, the conduct of our clinical trials, preclinical studies and manufacturing activities is dependent upon the availability of clinical trial sites, CROs, contract development and manufacturing organization, or CDMOs, researchers and investigators, regulatory agency personnel and logistics providers, all of which may be adversely affected by the COVID-19 pandemic.

Any negative impact that the COVID-19 pandemic has on enrolling or retaining patients in our clinical trials, the ability of our suppliers to provide materials for our product candidates, or the regulatory review process could cause delays with respect to product development activities, which could materially and adversely affect our ability to obtain marketing approval for and to commercialize our product candidates, increase our operating expenses, affect our ability to raise additional capital, and have a material adverse effect on our financial results.

We cannot provide assurance that some factors from the COVID-19 pandemic will not further delay or otherwise adversely affect our clinical development, research, manufacturing and business operations activities, as well as our business generally, in the future.

We and the third-party manufacturers, CROs and academic collaborators that we engage have faced in the past and may face in the future disruptions that could affect our ability to initiate and complete preclinical studies or clinical trials, including disruptions in procuring items that are essential for our research and development activities, such as, for example, raw materials used in the manufacture of our product candidates, laboratory supplies for our preclinical studies and clinical trials, or animals that are used for preclinical testing, in each case, for which there may be shortages because of ongoing efforts to address the COVID-19 pandemic. Three vaccines for COVID-19 have been granted Emergency Use Authorization by the FDA, and more are likely to be authorized in the coming months. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the products needed for our clinical trials, which could lead to delays in these trials. Additionally, the response to the COVID-19 pandemic may redirect resources with respect to regulatory and intellectual property matters in a way that would adversely impact our ability to pursue marketing approvals and protect our intellectual property. In addition, we may face impediments to regulatory meetings and potential approvals due to measures intended to limit in-person interactions.

In response to the COVID-19 pandemic and in accordance with direction from state and local governmental authorities, we have restricted access to our facility to those individuals who must perform critical research, translational medicine and laboratory support activities that must be completed on site, limited the number of such people that can be present at our facility at any one time, and required that most of our employees work remotely. In the event that governmental

authorities were to keep these restrictions in place for an extended period or impose further restrictions, our employees conducting research and development activities may not be able to access our laboratory space, and our core research activities may be significantly limited or curtailed, possibly for an extended period of time.

The COVID-19 pandemic continues to rapidly evolve, and its ultimate scope, duration and effects are unknown. The extent of the impact of the disruptions to our business, preclinical studies and clinical trials as a result of the COVID-19 pandemic will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the COVID-19 pandemic, travel restrictions and actions to contain the COVID-19 pandemic, such as social distancing and quarantines or lock-downs in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

The COVID-19 pandemic has already caused significant disruptions in the financial markets, and may continue to cause such disruptions, which could adversely impact our ability to raise additional funds through public offerings or private placements and may also impact the volatility of our stock price and trading in our stock. Moreover, it is possible the pandemic will significantly impact economies worldwide, which could result in adverse effects on our business and operations. We cannot be certain what the overall impact of the COVID-19 pandemic will be on our business and it has the potential to adversely affect our business, financial condition, results of operations and prospects.

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the research and development, clinical, financial, operational and other business expertise of our executive officers, as well as the other principal members of our management, scientific and clinical teams. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees. Recruiting and retaining qualified scientific, clinical, manufacturing, accounting, legal and sales and marketing personnel will also be critical to our success.

The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain marketing approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. Our success as a public company also depends on implementing and maintaining internal controls and the accuracy and timeliness of our financial reporting. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We expect to expand our development, manufacturing and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As we seek to advance our product candidates through clinical trials and commercialization, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities. We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, clinical, regulatory affairs and, if any product candidate receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion

of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our clinical development programs and the diseases our therapeutics are being developed to treat, and we intend to utilize appropriate social media in connection with our commercialization efforts following approval of our product candidates, if any. Social media practices in the biotechnology and biopharmaceutical industry continue to evolve and regulations and regulatory guidance relating to such use are evolving and not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us, along with the potential for litigation related to off-label marketing or other prohibited activities and heightened scrutiny by the FDA, the SEC and other regulators. For example, patients may use social media channels to comment on their experience in an ongoing blinded clinical trial or to report an alleged adverse event. If such disclosures occur, there is a risk that trial enrollment may be adversely impacted, that we may fail to monitor and comply with applicable adverse event reporting obligations or that we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our product candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. In addition, we may encounter attacks on social media regarding our company, management, product candidates or products. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to our business.

Our internal computer systems, or those of our third-party CROs that we may use in the future, or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product candidates' development programs.

Despite our implementation of security measures, our internal computer systems, and those of our CROs that we may use in the future, information technology suppliers and other contractors and consultants are vulnerable to damage from computer viruses, cyberattacks and other unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product candidate development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of any of our product candidates could be delayed.

Our operations or those of the third parties upon whom we depend might be affected by the occurrence of a natural disaster, pandemic or other catastrophic event.

We depend on our employees and consultants, CDMOs and CROs that we may use in the future, as well as regulatory agencies and other parties, for the continued operation of our business. While we maintain disaster recovery plans, they might not adequately protect us. Despite any precautions we take for natural disasters or other catastrophic events, these events, including terrorist attack, pandemics, hurricanes, fire, floods and ice and snowstorms, could result in significant disruptions to our research and development, preclinical studies, clinical trials, and, ultimately, commercialization of our products. Long-term disruptions in the infrastructure caused by events, such as natural disasters, the outbreak of war, the escalation of hostilities and acts of terrorism or other "acts of God," particularly involving cities in which we have offices, manufacturing or clinical trial sites, could adversely affect our businesses. Although we carry business interruption insurance policies and typically have provisions in our contracts that protect us in certain events, our coverage might not respond or be adequate to compensate us for all losses that may occur. Any natural disaster or catastrophic event affecting us, our CDMOs or CROs, regulatory agencies or other parties with which we are engaged could have a significant negative impact on our operations and financial performance.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

Upon completion of this offering, we will become subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded,

processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make a required related party transaction disclosure. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

We and our independent registered public accounting firm have identified material weaknesses in our internal control over financial reporting in conjunction with their audits of our financial statements for the years ended December 31, 2019 and 2020. If we are unable to remediate these material weakness, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business and the market price of our common stock.

In preparation of our consolidated financial statements to meet the requirements applicable to this offering, we and our independent registered public accounting firm identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

The material weaknesses identified related to:

(1) the fact that we did not have sufficient finance and accounting staff with U.S. generally accepted accounting principles technical and accounting expertise to evaluate and account for significant transactions and oversee our third-party consultants. As a result we did not design and maintain formal accounting policies, processes and controls to analyze, account for and disclose certain complex transactions, which led to inappropriate accounting conclusions associated with stock compensation expenses; and

(2) the fact that we lacked proper monitoring entity level controls and segregation of duties due to our small accounting staff.

We have implemented, and are continuing to implement, measures designed to improve internal control over financial reporting to remediate the control deficiencies that led to the material weaknesses, including the following:

- hiring an experienced Chief Financial Officer with experience serving as acting chief financial officer of a public company and serving as an audit partner at a major accounting firm;
- strengthening supervisory reviews by our financial management, and
- expanding our accounting and finance team to add additional qualified accounting and finance resources, which may include augmenting our finance team with third-party consultants that possess the required expertise to assist management with their review.

We cannot assure you that the measures we have taken to date, and actions we may take in the future, will be sufficient to remediate the control deficiencies that led to the material weaknesses in our internal control over financial reporting or that they will prevent or avoid potential future material weaknesses. In addition, neither our management nor an independent registered public accounting firm has performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act because no such evaluation has been required. Had we or our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, additional material weaknesses may have been identified. If we are unable to successfully remediate our existing or any future material weaknesses in our internal control over financial reporting, or identify any additional material weaknesses in the future, or otherwise fail to maintain an effective system of internal controls, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting, and the market price of our common stock may decline as a result.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, is designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could harm our business and have a negative effect on the trading price of our stock.

We will be required to disclose changes made in our internal controls and procedures on a quarterly basis and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an EGC under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. We could be an EGC for up to five years. Our assessment of internal controls and procedures may not detect material weaknesses in our internal control over financial reporting. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation, which could have a negative effect on the trading price of our stock.

Risks Related to Legal and Compliance Matters

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability and have to limit the commercialization of any approved products and/or our product candidates.

The use of our product candidates in clinical trials, and the sale of any product for which we obtain regulatory approval, exposes us to the risk of product liability claims. We face inherent risk of product liability related to the testing of our product candidates in human clinical trials, including liability relating to the actions and negligence of our investigators, and will face an even greater risk if we commercially sell any product candidates that we may develop. For example, we may be sued if any product candidate we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. Product liability claims might be brought against us by consumers, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of merit or eventual outcome, liability claims may result in:

- loss of revenue from decreased demand for our products and/or product candidates;
- impairment of our business reputation or financial stability;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- diversion of management attention;
- withdrawal of clinical trial participants and potential termination of clinical trial sites or entire clinical programs;
- the inability to commercialize our product candidates;
- significant negative media attention;
- decreases in our stock price;
- initiation of investigations and enforcement actions by regulators; and
- product recalls, withdrawals or labeling, marketing or promotional restrictions, including withdrawal of marketing approval.

We believe we have sufficient insurance coverage in place for our business operations. However, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We intend to expand our insurance coverage to include the sale of commercial products if we obtain FDA or comparable foreign regulatory approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing, or at all. Failure to obtain and retain sufficient product liability insurance at an acceptable cost could prevent or inhibit the commercialization of products we develop. On occasion, large judgments have been awarded in class action lawsuits based on therapeutics that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash, and materially harm our business, financial condition, results of operations, stock price and prospects.

We are subject to the U.S. Foreign Corrupt Practices Act and other anti-corruption laws, as well as import and export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures, and legal expenses, which could adversely affect our business, financial condition, results of operations, stock price and prospects.

Our operations are subject to anti-corruption laws, including the Foreign Corrupt Practices Act, or FCPA, and other anti-corruption laws that apply in countries where we do business. The FCPA and these other laws generally prohibit us and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We also may participate in collaborations and relationships with third parties whose actions, if non-compliant, could potentially subject us to liability under the FCPA or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the government of the United States, including applicable import and export control regulations, economic sanctions on countries and persons, anti-money laundering laws, customs requirements and currency exchange regulations, collectively referred to as the trade control laws.

We can provide no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws or other legal requirements, including trade control laws. If we are not in compliance with applicable anti-corruption laws or trade control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations, stock price and prospects. Likewise, any investigation of any potential violations of these anti-corruption laws or trade control laws by United States or other authorities could also have an adverse impact on our reputation, our business, financial condition, results of operations, stock price and prospects.

If we fail to comply with federal and state healthcare laws, including fraud and abuse and health and other information privacy and security laws, we could face substantial penalties and our business, financial condition, results of operations, stock price and prospects will be materially harmed.

We are subject to many federal and state healthcare laws, including those described in “Business—Government Regulation” such as the federal Anti-Kickback Statute, the federal civil and criminal False Claims Acts, the civil monetary penalties statute, the Medicaid Drug Rebate statute and other price reporting requirements, the Veterans Health Care Act of 1992, or VHCA HIPAA, the FCPA, the ACA and similar state laws. Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws, and regulations pertaining to fraud and abuse, reimbursement programs, government procurement, and patients’ rights are and will be applicable to our business. We would be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states and foreign jurisdictions in which we conduct our business. In the European Union, the data privacy laws are generally stricter than those which apply in the United States and include specific requirements for the collection of personal data of European Union persons or the transfer of personal data outside of the European Union to the United States to ensure that European Union standards of data privacy will be applied to such data.

If we or our operations, including our arrangements with physicians and other healthcare providers, some of whom receive share options or other financial interest in the business as compensation for services provided, are found to be in violation of any federal or state healthcare law, or any other governmental laws or regulations that apply to us, we may be subject to penalties, including civil, criminal, and administrative penalties, damages, fines, disgorgement, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from participation in U.S. federal or state health care programs, corporate integrity agreements, and the curtailment or restructuring of our operations, any of which could materially adversely affect our ability to operate our business and our financial results. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, it or they may be subject to criminal, civil or administrative sanctions, including but not limited to, exclusions from participation in government healthcare programs, which could also materially affect our business.

Although an effective compliance program can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Moreover, achieving and sustaining compliance with applicable federal, state and foreign privacy, data protection, security, reimbursement, and fraud laws may prove costly. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition.

Recent changes in tax law may adversely affect our business or financial condition. On December 22, 2017, the U.S. government enacted the Tax Cuts and Jobs Act, or TCJA, which significantly reformed the Internal Revenue Code of 1986, as amended, or the Code. The TCJA, among other things, contains significant changes to corporate taxation, including reducing the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limiting the tax deduction for net interest expense to 30% of adjusted taxable income (except for certain small businesses), limiting the deduction for NOLs arising in taxable years beginning after December 31, 2017 to 80% of current year taxable income and elimination of NOL carrybacks for losses arising in taxable years ending after December 31, 2017 (though any such NOLs may be carried forward indefinitely), imposing a one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, eliminating U.S. tax on foreign earnings (subject to certain important exceptions), allowing immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits.

As part of Congress' response to the COVID-19 pandemic, the Families First Coronavirus Response Act, or FFCR Act, was enacted on March 18, 2020, the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, was enacted on March 27, 2020, and COVID relief provisions were included in the Consolidated Appropriations Act, 2021 or CAA, which was enacted on December 27, 2020. Both contain numerous tax provisions. In particular, the CARES Act retroactively and temporarily (for taxable years beginning before January 1, 2021) suspends application of the 80%-of-income limitation on the use of NOLs, which was enacted as part of the TCJA. It also provides that NOLs arising in any taxable year beginning after December 31, 2017, and before January 1, 2021 are generally eligible to be carried back up to five years. The CARES Act also temporarily (for taxable years beginning in 2019 or 2020) relaxes the limitation of the tax deductibility for net interest expense by increasing the limitation from 30% to 50% of adjusted taxable income.

Regulatory guidance under the TCJA, the FFCR Act, the CARES Act and the CAA is and continues to be forthcoming, and such guidance could ultimately increase or lessen their impact on our business and financial condition. It is also likely that Congress will enact additional legislation in connection with the COVID-19 pandemic, some of which could have an impact on us. In addition, it is uncertain if and to what extent various states will conform to the TCJA, the FFCR Act, the Cares Act, or the CAA. We urge prospective investors in our common stock to consult with their legal and tax advisors with respect to any recently enacted tax legislation, or proposed changes in law, and the potential tax consequences of investing in or holding our common stock.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its equity ownership by 5% stockholders over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards

and other pre-change tax attributes to offset its post-change taxable income may be limited. As a result of our most recent private placements and other transactions that have occurred over the past three years, we may have experienced, and, upon closing of this offering, may experience, an "ownership change." We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As of December 31, 2020, we had U.S. federal and state net operating loss carryforwards of $8.8 million and $27.6 million, which begin to expire in 2027 and 2032, respectively. Additionally, as of December 31, 2019, we had U.S. federal and state research and development tax credit carryforwards of $0.7 million and $0.4 million respectively, which will begin to expire in 2036 and 2028, respectively, and which could be limited if we experience an "ownership change." The reduction of the corporate tax rate under the TCJA may cause a reduction in the economic benefit of our net operating loss carryforwards and other deferred tax assets available to us. Under the TCJA, federal net operating losses generated after December 31, 2017 will not be subject to expiration but will not be permitted to be carried back. In addition, under the TCJA, the amount of post-2017 net operating losses that we are permitted to deduct in any taxable year is limited to 80% of our taxable income in such year, where taxable income is determined without regard to the net operating loss deduction itself. Additionally, as of December 31, 2020, we had a U.S. federal net operating loss carryforward of $19.7 million which does not expire but is limited to an annual deduction equal to 80% of annual taxable income.

If the government or third-party payors fail to provide adequate coverage, reimbursement and payment rates for our product candidates, or if health maintenance organizations or long-term care facilities choose to use therapies that are less expensive or considered a better value, our revenue and prospects for profitability will be limited.

In both domestic and foreign markets, sales of our products will depend in part upon the availability of coverage and reimbursement from third-party payors. Such third-party payors include government health programs such as Medicare and Medicaid, managed care providers, private health insurers, and other organizations. Coverage decisions may depend upon clinical and economic standards that disfavor new therapeutic products when more established or lower cost therapeutic alternatives are already available or subsequently become available, even if our products are alone in a class. If reimbursement is not available, or is available only to limited levels, our product candidates may be competitively disadvantaged, and we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain a market share sufficient to realize a sufficient return on our or their investments. Alternatively, securing favorable reimbursement terms may require us to compromise pricing and prevent us from realizing an adequate margin over cost.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved therapeutics. Marketing approvals, pricing, and reimbursement for new therapeutic products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a therapeutic before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription biopharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, which may negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our or their investment in one or more product candidates, even if our product candidates obtain marketing approval. Our ability to commercialize our product candidates will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Regulatory authorities and third-party payors, such as private health insurers, and health maintenance organizations, decide which medications they will cover and establish reimbursement levels. The healthcare industry is acutely focused on cost containment, both in the United States and elsewhere. Several third-party payors are requiring that companies provide them with predetermined discounts from list prices, are using preferred drug lists to leverage greater discounts in competitive classes, are disregarding therapeutic differentiators within classes, are challenging the prices charged for therapeutics, and are negotiating price concessions based on performance goals.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of

coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for our products or product candidates for which we receive regulatory approval may not be available or adequate in either the United States or international markets, which could have a negative effect on our business, financial condition, results of operations, stock price and prospects.

Assuming coverage is approved, the resulting reimbursement payment rates might not be adequate. If payors subject our product candidates to maximum payment amounts, or impose limitations that make it difficult to obtain reimbursement, providers may choose to use therapies which are less expensive when compared to our product candidates. Additionally, if payors require high copayments, beneficiaries may seek alternative therapies. We may need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any products to the satisfaction of hospitals, other target customers and their third-party payors. Such studies might require us to commit a significant amount of management time and financial and other resources. Our products might not ultimately be considered cost-effective. Adequate third-party coverage and reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development.

In addition, federal programs impose penalties on manufacturers of therapeutics in the form of mandatory additional rebates and/or discounts if commercial prices increase at a rate greater than the Consumer Price Index-Urban, and these rebates and/or discounts, which can be substantial, may impact our ability to raise commercial prices. A few states have also passed or are considering legislation intended to prevent significant price increases. Regulatory authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability to sell our product candidates profitably. These payors may not view our products, if any, as cost-effective, and coverage and reimbursement may not be available to our customers, or may not be sufficient to allow our products, if any, to be marketed on a competitive basis. Cost-control initiatives could cause us to decrease, discount, or rebate a portion of the price we, or they, might establish for products, which could result in lower than anticipated product revenues. If the realized prices for our products, if any, decrease or if governmental and other third-party payors do not provide adequate coverage or reimbursement, our prospects for revenue and profitability will suffer.

There may also be delays in obtaining coverage and reimbursement for newly approved therapeutics, and coverage may be more limited than the indications for which the product is approved by the FDA or comparable foreign regulatory authorities. Such delays have made it increasingly common for manufacturers to provide newly approved drugs to patients experiencing coverage delays or disruption at no cost for a limited period in order to ensure that patients are able to access the drug. Moreover, eligibility for reimbursement does not imply that any therapeutic will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new therapeutics, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary, by way of example, according to the use of the product and the clinical setting in which it is used. Reimbursement rates may also be based on reimbursement levels already set for lower cost products or may be incorporated into existing payments for other services.

In addition, third-party payors are increasingly requiring higher levels of evidence of the benefits and clinical outcomes of new technologies, benchmarking against other therapies, seeking performance-based discounts, and challenging the prices charged. We cannot be sure that coverage will be available for any product candidate that we commercialize and, if available, that the reimbursement rates will be adequate. An inability to promptly obtain coverage and adequate payment rates from both government-funded and private payors for any of our product candidates for which we obtain marketing approval could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

We are subject to new legislation, regulatory proposals and healthcare payor initiatives that may increase our costs of compliance, and adversely affect our ability to market our products, obtain collaborators and raise capital.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any products for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be

adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved products.

In particular, in 2010, the ACA was enacted, which, among other things, subjected biologic products to potential competition by lower-cost biosimilars; addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjected manufacturers to new annual fees and taxes for certain branded prescription drugs; created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and provided incentives to programs that increase the federal government's comparative effectiveness research.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, various portions of the ACA are currently undergoing legal and constitutional challenges in the United States Supreme Court. Additionally, the Trump administration issued various Executive Orders which eliminated cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices, and Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what affect further changes to the ACA would have on our business, especially given the new presidential administration.

Legislative changes have been proposed and adopted since the ACA was enacted in 2010. These changes include, among other things, aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went effective on April 1, 2013, and, due to subsequent legislative amendments, will remain in effect through 2030 unless additional Congressional action is taken. Pursuant to the CARES Act, as well as subsequent legislation, these reductions have been suspended from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic. Proposed legislation, if passed, would extend this suspension until the end of the pandemic. In addition, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Trump administration's budget proposal for fiscal year 2021 included a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Further, the Trump administration also previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. However, it is unclear whether the Biden administration will challenge, reverse, revoke or otherwise modify these executive and administrative actions after January 20, 2021. In addition, there have been several changes to the 340B drug pricing program, which imposes ceilings on prices that drug manufacturers can charge for medications sold to certain health care facilities. On December 27, 2018, the District Court for the District of Columbia invalidated a reimbursement formula change under the 340B drug pricing program, and CMS subsequently altered the fiscal year 2019 and 2018 reimbursement formula on specified covered outpatient drugs (SCODs). The court ruled this change was not an "adjustment" which was within the Secretary's discretion to make but was instead a fundamental change in the

reimbursement calculation. However, most recently, on July 31, 2020, the U.S. Court of Appeals for the District of Columbia Circuit overturned the district court's decision and found that the changes were within the Secretary's authority. On September 14, 2020, the plaintiffs-appellees filed a Petition for Rehearing En Banc (i.e., before the full court), but was denied on October 16, 2020. It is unclear how these developments could affect covered hospitals who might purchase our future products and affect the rates we may charge such facilities for our approved products in the future, if any.

On July 24, 2020 and September 13, 2020, former President Trump announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. In response, the FDA released a final rule on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and will apply in all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. The Interim Final Rule has not been finalized and is subject to revision and challenge.

Additionally, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, Congress has indicated that it will continue to seek new legislative measures to control drug costs.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that the ACA, as well as other federal and state healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria, increased regulatory burdens and operating costs, decreased net revenue from our biopharmaceutical products, decreased potential returns from our development efforts, and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from commercializing our products and being able to generate revenue, and we could be prevented from or significantly delayed in achieving profitability.

In addition, there have been a number of other legislative and regulatory proposals aimed at changing the biopharmaceutical industry. For instance, the Drug Quality and Security Act imposes obligations on manufacturers of biopharmaceutical products related to product tracking and tracing. Among the requirements of this legislation, manufacturers are required to provide certain information regarding the product to individuals and entities to which product ownership is transferred, will be required to label products with a product identifier, and are required keep certain records regarding the product. The transfer of information to subsequent product owners by manufacturers is also required to be done electronically. Manufacturers are also being required to verify that purchasers of the manufacturers' products are appropriately licensed. Further, manufacturers have product investigation, quarantine, disposition, and FDA, other comparable foreign regulatory authorities, and trading partner notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products that would result in serious adverse health consequences of death to humans, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

Compliance with the federal track and trace requirements may increase our operational expenses and impose significant administrative burdens. As a result of these and other new proposals, we may determine to change our current manner of operation, provide additional benefits or change our contract arrangements, any of which could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

Our employees, independent contractors, consultants, commercial partners, principal investigators or CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees, independent contractors, consultants, commercial partners, principal investigators, contract manufacturing organizations or CROs could include intentional, reckless, negligent, or unintentional failures to comply with FDA regulations, comply with applicable fraud and abuse laws, provide accurate information to the FDA, properly calculate pricing information required by federal programs, report financial information or data accurately or disclose unauthorized activities to us. This misconduct could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter this type of misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Moreover, it is possible for a whistleblower to pursue a False Claims Act case against us even if the government considers the claim unmeritorious and declines to intervene, which could require us to incur costs defending against such a claim. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations, stock price and prospects, including the imposition of significant fines or other sanctions.

Violations of or liabilities under environmental, health and safety laws and regulations could subject us to fines, penalties or other costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures, the handling, use, storage, treatment and disposal of hazardous materials and wastes and the cleanup of contaminated sites. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. We would incur substantial costs as a result of violations of or liabilities under environmental requirements in connection with our operations or property, including fines, penalties and other sanctions, investigation and cleanup costs and third-party claims. Although we generally contract with third parties for the disposal of hazardous materials and wastes from our operations, we cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

Risks Related to Our Reliance on Third Parties

For certain product candidates, we depend, or will depend, on development and commercialization collaborators to develop and conduct clinical trials with, obtain regulatory approvals for, and if approved, market and sell product candidates. If such collaborators fail to perform as expected, the potential for us to generate future revenue from such product candidates would be significantly reduced and our business would be harmed.

For certain product candidates, we depend, or will depend, on our development and commercial collaborators to develop, conduct clinical trials of, and, if approved, commercialize product candidates. We have entered into a collaboration with Bristol-Myers Squibb Company, or BMS, and the Adult Brain Tumor Consortium, or ABTC, for a Phase 1b clinical trial in malignant glioma patients. We cannot provide assurance that our collaborators will be successful in or that they will devote sufficient resources to these collaborations. If our current or future

collaboration and commercialization partners do not perform in the manner we expect or fail to fulfill their responsibilities in a timely manner, or at all, if our agreements with them terminate or if the quality or accuracy of the clinical data they obtain is compromised, the clinical development, regulatory approval and commercialization efforts related to their and our product candidates and products could be delayed or terminated and it could become necessary for us to assume the responsibility at our own expense for the clinical development of such product candidates. Moreover, our ability to generate revenues from these collaborations and product candidates will depend on such collaborators' abilities to perform in the manner we expect or fulfill their responsibilities in a timely manner, and delays by collaborators, or caused by other collaboration contract obligations, may result in a delay of our ability to disclose data.

Our current collaborations and any future collaborations that we enter into are subject to numerous risks, including:

- collaborators have significant discretion in determining the efforts and resources that they will apply to the collaborations;
- collaborators may not perform their obligations as expected or fail to fulfill their responsibilities in a timely manner, or at all;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on preclinical studies or clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay preclinical studies or clinical trials, provide insufficient funding for clinical trials, stop a preclinical study or clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could fail to make timely regulatory submissions for a product candidate;
- we may not have access to, or may be restricted from disclosing, certain information regarding product candidates being developed or commercialized under a collaboration and, consequently, may have limited ability to inform our shareholders about the status of such product candidates;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- the collaborations may not result in product candidates to develop and/or preclinical studies or clinical trials conducted as part of the collaborations may not be successful;
- product candidates developed with collaborators may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to stop commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of any such product candidate; and
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation.

In addition, certain collaboration and commercialization agreements provide our collaborators with rights to terminate such agreements, which rights may or may not be subject to conditions, and which rights, if exercised, would adversely affect our product development efforts and could make it difficult for us to attract new collaborators. For example, our license agreement with The Brigham and Women's Hospital, or BWH, may be terminated by BWH for our failure to pay, our failure to maintain proper insurance in accordance with the agreement, if we file for bankruptcy or if we remain in default for non-financial reasons following a specified cure period to remedy the breach. In the event of the termination of any collaboration or commercialization agreement, we would likely be required to limit the size and scope of efforts for the development and commercialization of such product candidates or products; we would likely be required to seek additional financing to fund further development or identify alternative strategic collaborations; our potential to generate future revenue from royalties and milestone payments

from such product candidates or products would be significantly reduced, delayed or eliminated; and it could have an adverse effect on our business and future growth prospects. Our rights to recover tangible and intangible assets and intellectual property rights needed to advance a product candidate or product after termination of a collaboration may be limited by contract, and we may not be able to advance a program post-termination.

As a result of the foregoing, our current and any future collaboration agreements may not lead to development or commercialization of our product candidates in the most efficient manner or at all. If a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our reputation in the business and financial communities could be adversely affected. Any failure to successfully develop or commercialize our product candidates pursuant to our current or any future collaboration agreements could have a material and adverse effect on our business, financial condition, results of operations and prospects.

If conflicts arise with our development and commercialization collaborators or licensors, they may act in their own self-interest, which may be adverse to the interests of our company.

We may in the future experience disagreements with our development and commercialization collaborators or licensors. Conflicts may arise in our collaboration and license arrangements with third parties due to one or more of the following:

- disputes with respect to milestone, royalty and other payments that are believed due under the applicable agreements;
- disagreements with respect to the ownership of intellectual property rights or scope of licenses;
- disagreements with respect to the scope of any reporting obligations;
- disagreements with respect to contract interpretation or the preferred course of development;
- unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and commercialization activities, or to permit public disclosure of these activities; and
- disputes with respect to a collaborator's or our development or commercialization efforts with respect to our products and product candidates.

Conflicts with our development and commercialization collaborators or licensors could materially adversely affect our business, financial condition or results of operations and future growth prospects.

We rely on third parties, including independent clinical investigators and CROs to conduct and sponsor some of the clinical trials of our product candidates. Any failure by a third party to meet its obligations with respect to the clinical development of our product candidates may delay or impair our ability to obtain regulatory approval for our product candidates.

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators, academic partners, medical institutions, regulatory affairs consultants and third-party CROs, to conduct our preclinical studies and clinical trials, including in some instances sponsoring such clinical trials, and to engage with regulatory authorities and monitor and manage data for our ongoing preclinical and clinical programs. While we have, or will have, agreements governing the activities of such third parties, we will control only certain aspects of their activities and have limited influence over their actual performance.

Any of these third parties may terminate their engagements with us under certain circumstances. We may not be able to enter into alternative arrangements or do so on commercially reasonable terms. In addition, there is a natural transition period when a new contract research organization begins work. As a result, delays would likely occur, which could negatively impact our ability to meet our expected clinical development timelines and harm our business, financial condition and prospects.

We remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, the Competent

Authorities of the Member States of the EEA and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we fail to exercise adequate oversight over any of our academic partners or CROs or if we or any of our academic partners or CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements, or for any other reasons, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon a regulatory inspection of us, our academic partners or our CROs or other third parties performing services in connection with our clinical trials, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under applicable cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Furthermore, the third parties conducting clinical trials on our behalf are not our employees, and except for remedies available to us under our agreements with such contractors, we cannot control whether or not they devote sufficient time, skill and resources to our ongoing development programs. These contractors may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could impede their ability to devote appropriate time to our clinical programs. If these third parties, including clinical investigators, do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates. If that occurs, we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

In addition, with respect to investigator-sponsored trials that are being or may be conducted, we do not control the design or conduct of these trials, and it is possible that the FDA or EMA will not view these investigator-sponsored trials as providing adequate support for future clinical trials or market approval, whether controlled by us or third parties, for any one or more reasons, including elements of the design or execution of the trials or safety concerns or other trial results. We expect that such arrangements will provide us certain information rights with respect to the investigator-sponsored trials, including the ability to obtain a license to obtain access to use and reference the data, including for our own regulatory submissions, resulting from the investigator-sponsored trials. However, we do not have control over the timing and reporting of the data from investigator-sponsored trials, nor do we own the data from the investigator-sponsored trials. If we are unable to confirm or replicate the results from the investigator-sponsored trials or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development. Further, if investigators or institutions breach their obligations with respect to the clinical development of our product candidates, or if the data proves to be inadequate compared to the firsthand knowledge we might have gained had the investigator-sponsored trials been sponsored and conducted by us, then our ability to design and conduct any future clinical trials ourselves may be adversely affected. Additionally, the FDA or EMA may disagree with the sufficiency of our right of reference to the preclinical, manufacturing or clinical data generated by these investigator-sponsored trials, or our interpretation of preclinical, manufacturing or clinical data from these investigator-sponsored trials. If so, the FDA or EMA may require us to obtain and submit additional preclinical, manufacturing, or clinical data.

If the manufacturers upon which we may rely fail to produce our product candidates in the volumes that we require on a timely basis, or fail to comply with stringent regulations applicable to biopharmaceutical manufacturers, we may face delays in the development and commercialization of, or be unable to meet demand for, our product candidates and may lose potential revenues.

We expect to develop commercial manufacturing capabilities at our facility in Needham, Massachusetts and at third-party manufacturers. We may rely on third-party contract manufacturers to manufacture our clinical trial product supplies and for commercial scale manufacturing. We also expect to continue to rely on third-party contractors for certain portions of our manufacturing process in the event our manufacturing facility is complete and fully operational. There can be no assurance that our clinical development will not be limited, interrupted, or of satisfactory quality or continue to be available at acceptable prices. In particular, any replacement of our contract manufacturer could require significant effort and expertise because there may be a limited number of qualified

replacements. Any delays in obtaining adequate supplies of our product candidates that meet the necessary quality standards, including delays caused by the COVID-19 pandemic, may delay our development or commercialization.

We may not succeed in our efforts to establish manufacturing relationships or other alternative arrangements for any of our product candidates or programs. Our product candidates may compete with other products and product candidates for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that are both capable of manufacturing and filling our viral product for us and willing to do so. If our existing third-party manufacturers, or the third parties that we engage in the future, should cease to work with us, we likely would experience delays in obtaining sufficient quantities of our product candidates for us to meet commercial demand or to advance our clinical trials while we identify and qualify replacement suppliers. If for any reason we are unable to obtain adequate supplies of our product candidates or the therapeutic substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively. Further, even if we do establish such collaborations or arrangements, our third-party manufacturers may breach, terminate, or not renew these agreements.

Any problems or delays we experience in preparing for commercial scale manufacturing of a product candidate or component may result in a delay in product development timelines and FDA or comparable foreign regulatory authority approval of the product candidate or may impair our ability to manufacture commercial quantities or such quantities at an acceptable cost and quality, which could result in the delay, prevention, or impairment of clinical development and commercialization of our product candidates and may materially harm our business, financial condition, results of operations, stock price and prospects.

The manufacture of biopharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of therapeutics often encounter difficulties in production, particularly in scaling up initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel or key raw materials, and compliance with strictly enforced federal, state, and foreign regulations. Our contract manufacturers may not perform as agreed. If our manufacturers were to encounter these or other difficulties, our ability to provide product candidates to patients in our clinical trials could be jeopardized.

Contract manufacturers of our product candidates may be unable to comply with our specifications, applicable cGMP requirements or other FDA, state or foreign regulatory requirements. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of a product candidate that may not be detectable in final product testing. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, they will not be able to secure or maintain regulatory approval for their manufacturing facilities. Any such deviations may also require remedial measures that may be costly and/or time consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business. Any delays in obtaining products or product candidates that comply with the applicable regulatory requirements may result in delays to clinical trials, product approvals, and commercialization. It may also require that we conduct additional studies.

While we are ultimately responsible for the manufacturing of our product candidates and therapeutic substances, other than through our contractual arrangements, we have little control over our manufacturers' compliance with these regulations and standards. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Any new manufacturers would need to either obtain or develop the necessary manufacturing know-how, and obtain the necessary equipment and materials, which may take substantial time and investment. We must also receive FDA approval for the use of any new manufacturers for commercial supply.

A failure to comply with the applicable regulatory requirements, including periodic regulatory inspections, may result in regulatory enforcement actions against our manufacturers or us (including fines and civil and criminal penalties,

including imprisonment) suspension or restrictions of production, injunctions, delay or denial of product approval or supplements to approved products, clinical holds or termination of clinical trials, warning or untitled letters, regulatory authority communications warning the public about safety issues with the product candidate, refusal to permit the import or export of the products, product seizure, detention, or recall, operating restrictions, suits under the civil False Claims Act, corporate integrity agreements, consent decrees, withdrawal of product approval, environmental or safety incidents and other liabilities. If the safety of any quantities supplied is compromised due to our manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

Any failure or refusal to supply our product candidates or components for our product candidates that we may develop could delay, prevent or impair our clinical development or commercialization efforts. Any change in our manufacturers could be costly because the commercial terms of any new arrangement could be less favorable and because the expenses relating to the transfer of necessary technology and processes could be significant.

We have completed and may in the future complete related party transactions that were not and may not be conducted on an arm's length basis.

We have in the past and continue to be party to certain transactions with certain entities affiliated with Estuardo Aguilar-Cordova, our founder and Chief Scientific Officer, and Laura Aguilar, our Chief Medical Officer. For instance, we have entered into an exclusive license agreement with Ventagen, LLC (Ventagen), an entity owned in part (49.5%), though not managed, by Estuardo Aguilar-Cordova and Laura Aguilar, for the use of worldwide patent rights and know-how owned or controlled by us which cover applicable technology utilizing the delivery method of the herpes derived TK protein to tumors or other tissues via a viral vector.

In January 2008, we entered into an operating lease agreement with a term through December 31, 2022 with Ellka Holdings, LLC, or Ellka, for the space in which we operated in Auburndale, MA. In May 2016, we entered into a second lease agreement with Ellka for living space for employees, also in Auburndale, MA. We entered into a second lease for this space on July 26, 2018, which expired on July 31, 2019. Ellka was originally established in 2007 as an LLC for the purpose of acquiring and managing investment properties owned by Laura Aguilar and Estuardo Aguilar-Cordova and their children's trusts. Ellka is owned and operated by Laura Aguilar and Estuardo Aguilar Cordova and members of their immediate family. Although we believe that these transactions were conducted on an arm's length basis, it is possible that the terms were less favorable to us than they might have been in a transaction with an unrelated party.

As of June 30, 2021, Estuardo Aguilar-Cordova and Laura Aguilar beneficially owned 7,986,577 shares of our common stock, or approximately 42.5% of our total outstanding capital stock as of such date. Accordingly, they will continue to have significant influence over all business decisions, including with respect to such matters as amendments to our charter, other fundamental corporate transactions, such as mergers, asset sales, and the sale of the Company, and otherwise will be able to influence our business and affairs. In connection with this offering, we intend to adopt a written related-person transactions policy that sets forth our policies and procedures regarding the identification, review, consideration and oversight of related-person transactions.

The transition of our manufacturing operations to our new facility and to a third-party contract manufacturer may result in further delays or expenses, and we may not experience the anticipated operating efficiencies.

We have commissioned and are in the process of the build-out of and have successfully completed our first two tech transfers at, our approximately 2,600 square foot manufacturing facility that is part of our corporate headquarters in Needham, Massachusetts at which we intend to operate our own manufacturing facility in order to secure supplies for pivotal studies. This facility is intended to give us control over key aspects of the supply chain for our products and product candidates. We may not experience the anticipated operating efficiencies as we commence manufacturing operations at the new facility and we may also use contract manufacturers for our products and product candidates to ensure adequate supply. Any such delays may disrupt or delay the supply of our product candidates if we have not maintained a sufficient backup supply of our product candidates through third-party manufacturers. Moreover, changing manufacturing facilities may also require that we conduct additional studies, make notifications to the regulatory authorities, make additional filings to the regulatory authorities, and obtain regulatory authority approval for the new facilities, which may be delayed or which we may never receive. We will further need to comply with the FDA's and applicable foreign regulatory authorities' cGMP requirements for the production of our product candidates for clinical trials and, if approved, commercial supply, and will be subject to

FDA and comparable foreign regulatory authority inspection. These requirements include the qualification and validation of our manufacturing equipment and processes. We may not be able to develop or acquire the internal expertise and resources necessary for compliance with these requirements. If we fail to achieve the operating efficiencies that we anticipate, our manufacturing and operating costs may be greater than expected, which could have a material adverse impact on our operating results.

In operating our own manufacturing facility, we may be forced to devote greater resources and management time than anticipated, particularly in areas relating to operations, quality, regulatory, facilities and information technology. If we experience unanticipated employee turnover in any of these areas, we may not be able to effectively manage our ongoing manufacturing operations and we may not achieve the operating efficiencies that we anticipate from the new facility, which may negatively affect our product development timeline.

Any such problems could result in the delay, prevention, or impairment of clinical development and commercialization of our product candidates and may materially harm our business, financial condition, results of operations, stock price and prospects.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to manufacture our product candidates, and because we collaborate with various organizations and academic institutions on the development of our product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets.

Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

In addition, these agreements typically restrict the ability of our collaborators, advisors, employees and consultants to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by us, although in some cases we may share these rights with other parties. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

Risks Related to Intellectual Property

Our rights to develop and commercialize certain of our product candidates are subject and may in the future be subject, in part, to the terms and conditions of licenses granted to us by third parties. If we fail to comply with our obligations under our current or future intellectual property license agreements or otherwise experience disruptions to our business relationships with our current or any future licensors, we could lose intellectual property rights that are important to our business.

We are and expect to continue to be reliant upon third-party licensors for certain patent and other intellectual property rights that are important or necessary to the development of some of our technology and product candidates. For example, we rely on licenses from BWH and Periphagen to certain patent rights. These license agreements impose, and we expect that any future license agreement will impose, specified diligence, milestone

payment, royalty, commercialization, development and other obligations on us and require us to meet development timelines, or to exercise diligent or commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses. For more information on the terms of these license agreements, see “Business—Intellectual Property—License Agreements.”

Furthermore, our licensors have, or may in the future have, the right to terminate a license if we materially breach the agreement and fail to cure such breach within a specified period or in the event we undergo certain bankruptcy events. In spite of our best efforts, our current or any future licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements. If our license agreements are terminated, we may lose our rights to develop and commercialize certain of our product candidates and technology, lose patent protection, experience significant delays in the development and commercialization of certain of our product candidates and technology, and incur liability for damages. If these in-licenses are terminated, or if the underlying intellectual property fails to provide the intended exclusivity, our competitors or other third parties could have the freedom to seek regulatory approval of, and to market, products and technologies identical or competitive to ours and we may be required to cease our development and commercialization of certain of our product candidates and technology. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties, including our competitors, to receive licenses to a portion of the intellectual property that is subject to our existing licenses and to compete with any product candidates we may develop and our technology. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- our or our licensors’ ability to obtain, maintain and defend intellectual property and to enforce intellectual property rights against third parties;
- the extent to which our technology, product candidates and processes infringe, misappropriate or otherwise violate the intellectual property of the licensor that is not subject to the license agreement;
- the sublicensing of patent and other intellectual property rights under our license agreements;
- our diligence, development, regulatory, commercialization, financial or other obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our current or future licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, our license agreements are, and future license agreements are likely to be, complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our diligence, development, regulatory, commercialization, financial or other obligations under the relevant agreement. In addition, if disputes over intellectual property that we have licensed or any other dispute related to our license agreements prevent or impair our ability to maintain our current license agreements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates and technology. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

License agreements we may enter into in the future may be non-exclusive. Accordingly, third parties may also obtain non-exclusive licenses from such licensors with respect to the intellectual property licensed to us under such license agreements. Accordingly, these license agreements may not provide us with exclusive rights to use such licensed patent and other intellectual property rights, or may not provide us with exclusive rights to use such patent and other intellectual property rights in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and any product candidates we may develop in the future.

Moreover, some of our in-licensed patent and other intellectual property rights may in the future be subject to third-party interests such as co-ownership. If we are unable to obtain an exclusive license to such third-party co-owners’

interest, in such patent and other intellectual property rights, such third-party co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. We or our licensors may need the cooperation of any such co-owners of our licensed patent and other intellectual property rights in order to enforce them against third parties, and such cooperation may not be provided to us or our licensors.

Additionally, we may not have complete control over the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications that we license from third parties. It is possible that our licensors' filing, prosecution and maintenance of the licensed patents and patent applications, enforcement of patents against infringers or defense of such patents against challenges of validity or claims of enforceability may be less vigorous than if we had conducted them ourselves, and accordingly, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If our licensors fail to file, prosecute, maintain, enforce and defend such patents and patent applications, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, our right to develop and commercialize any of our technology and any product candidates we may develop that are the subject of such licensed rights could be adversely affected and we may not be able to prevent competitors or other third parties from making, using and selling competing products.

Furthermore, our owned and in-licensed patent rights may be subject to a reservation of rights by one or more third parties. When new technologies are developed with government funding, in order to secure ownership of patent rights related to the technologies, the recipient of such funding is required to comply with certain government regulations, including timely disclosing the inventions claimed in such patent rights to the U.S. government and timely electing title to such inventions. A failure to meet these obligations may lead to a loss of rights or the unenforceability of relevant patents or patent applications.

Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

Our business will depend in large part on obtaining and maintaining patent, trademark and trade secret protection of our proprietary technologies and our product candidates, their respective components, synthetic intermediates, formulations, combination therapies, methods used to manufacture them and methods of treatment, as well as successfully defending these patents against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents that cover these activities and whether a court would issue an injunctive remedy. If we are unable to secure and maintain patent protection for any product or technology we develop, or if the scope of the patent protection secured is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize any product candidates we may develop may be adversely affected.

The patenting process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we may not pursue, obtain, or maintain patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensors or licensees.

The strength of patents in the biotechnology and biopharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our technology, including our product candidates, or prevent others from designing around our claims. If the breadth or strength of protection provided by the patent applications and patents we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our

product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced.

We cannot be certain that we were the first to file any patent application related to our technology and directed to our product candidates, and, if we were not, we may be precluded from obtaining patent protection for our technology, including our product candidates.

We cannot be certain that we are the first to invent the inventions covered by pending patent applications and patents, and, if we are not, we may be subject to priority disputes. Furthermore, for United States applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the United States Patent and Trademark Office, or USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications and patents. Similarly, for United States applications in which at least one claim is not entitled to a priority date before March 16, 2013, derivation proceedings can be instituted to determine whether the subject matter of a patent claim was derived from a prior inventor's disclosure.

We may be required to disclaim part or all of the term of certain patents or all of the term of certain patent applications. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent or patent application claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable or that even if found valid and enforceable, would adequately protect our product candidates, or would be found by a court to be infringed by a competitor's technology or product. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities, and consider that we are free to operate in relation to our product candidates, but our competitors may achieve issued claims, including in patents we consider to be unrelated, which block our efforts or may potentially result in our product candidates or our activities infringing such claims. The possibility exists that others will develop products which have the same effect as our products on an independent basis which do not infringe our patents or other intellectual property rights, or will design around the claims of patents that may issue that cover our products.

Recent or future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. Under the enacted Leahy-Smith America Invents Act, or America Invents Act, enacted in 2013, the United States moved from a "first to invent" to a "first-to-file" system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a new post-grant review system. The effects of these changes are currently unclear as the USPTO only recently developed new regulations and procedures in connection with the America Invents Act and many of the substantive changes to patent law, including the "first-to-file" provisions, only became effective in March 2013. In addition, the courts have yet to address many of these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make or use compounds that are similar to the compositions of our product candidates but that are not covered by the claims of our patents or those of our licensors;
- we or our licensors, as the case may be, may fail to meet our obligations to the U.S. government in regards to any in-licensed patents and patent applications funded by U.S. government grants, leading to the loss of patent rights;

- we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our pending patent applications will not result in issued patents;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents, as the case may be, or parts of our or their patents;
- it is possible that others may circumvent our owned or in-licensed patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;
- the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our product candidates;
- our owned, co-owned, or in-licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges by third parties;
- the inventors of our owned, co-owned, or in-licensed patents or patent applications may become involved with competitors, develop products or processes which design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;
- the co-owners of certain of our patent applications may become involved with, or license or assign the co-owned applications to competitors , or become hostile to us or the patents or patent applications on which they are named as co-owners;
- it is possible that our owned or in-licensed patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;
- we have engaged in scientific collaborations in the past, and will continue to do so in the future. Such collaborators may develop adjacent or competing products to ours that are outside the scope of our patents;
- we may not develop additional proprietary technologies for which we can obtain patent protection;
- it is possible that product candidates or diagnostic tests we develop may be covered by third parties' patents or other exclusive rights; or
- the patents of others may have an adverse effect on our business.

We may enter into license or other collaboration agreements in the future that may impose certain obligations on us. If we fail to comply with our obligations under such future agreements with third parties, we could lose license rights that may be important to our future business.

In connection with our efforts to expand our pipeline of product candidates, we may enter into certain licenses or other collaboration agreements in the future pertaining to the in-license of rights to additional candidates. Such agreements may impose various diligence, milestone payment, royalty, insurance or other obligations on us. If we fail to comply with these obligations, our licensor or collaboration partners may have the right to terminate the relevant agreement, in which event we would not be able to develop or market the products covered by such licensed intellectual property.

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

In addition, we may have limited control over the maintenance and prosecution of these in-licensed patents and patent applications, or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by any future licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that is licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than had we conducted them ourselves.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to patent protection, we rely heavily upon know-how and trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third-parties, to protect our confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third-party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. For example, our clinical development strategy includes the testing of live tissue samples, and our techniques for preserving and testing these samples are proprietary and confidential. If one or more third parties obtain or are otherwise able to replicate these techniques, an important feature and differentiator of our clinical development strategy will become available to potential competitors. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

In addition, courts outside the United States are sometimes less willing to protect trade secrets. If we choose to go to court to stop a third-party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology.

Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In addition, we take other appropriate precautions, such as physical and

technological security measures, to guard against misappropriation of our proprietary technology by third parties. We have also adopted policies and conduct training that provides guidance on our expectations, and our advice for best practices, in protecting our trade secrets.

Third-party claims of intellectual property infringement may prevent or delay our product discovery and development efforts.

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and biopharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, *inter partes* review, post grant review, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and/or proprietary technologies infringe their intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and biopharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

If a third-party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third-party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third-party licenses its product rights to us, which it is not required to do;
- if a license is available from a third-party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products and any license that is available may be non-exclusive, which could result in our competitors gaining access to the same intellectual property; and
- redesigning our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure.

Our collaborators may assert ownership or commercial rights to inventions they develop from research we support or that we develop from our use of the tissue samples or other biological materials, which they provide to us, or otherwise arising from the collaboration.

We collaborate with several institutions, universities, medical centers, physicians and researchers in scientific matters and expect to continue to enter into additional collaboration agreements. In certain cases, we do not have written agreements with these collaborators, or the written agreements we have do not cover intellectual property

rights. Also, we rely on numerous third parties to provide us with tissue samples and biological materials that we use to conduct our research activities and develop our product candidates. If we cannot successfully negotiate sufficient ownership and commercial rights to any inventions that result from our use of a third-party collaborator's materials, or if disputes arise with respect to the intellectual property developed with the use of a collaborator's samples, or data developed in a collaborator's study, we may be limited in our ability to capitalize on the market potential of these inventions or developments.

Third parties may assert that we are employing their proprietary technology without authorization.

There may be third-party patents of which we are currently unaware with claims to compositions of matter, materials, formulations, methods of manufacture or methods for treatment that encompass the composition, use or manufacture of our product candidates. There may be currently pending patent applications of which we are currently unaware which may later result in issued patents that our product candidates or their use or manufacture may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patent were held by a court of competent jurisdiction to cover our product candidates, intermediates used in the manufacture of our product candidates or our materials generally, aspects of our formulations or methods of use, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information, misappropriated trade secrets, or are in breach of non-competition or non-solicitation agreements with our competitors.

As is common in the biotechnology and biopharmaceutical industries, we employ individuals who were previously employed at universities or other biotechnology or biopharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, and although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. We may also be subject to claims that we caused an employee to breach the terms of their non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor or other party. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or

other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

We may not be successful in obtaining or maintaining necessary rights to develop any future product candidates on acceptable terms.

Because our programs may involve additional product candidates that may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights.

Our product candidates may also require specific formulations to work effectively and efficiently and these rights may be held by others. We may develop products containing our compounds and pre-existing biopharmaceutical compounds. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

Additionally, we sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our current or future licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question or for other reasons. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

We may choose to challenge the patentability of claims in a third-party's U.S. patent by requesting that the USPTO review the patent claims in an *ex-parte* re-examination, *inter partes* review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third-party's patent in patent opposition proceedings in the European Patent Office, or EPO, or other foreign patent office. The costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third-party alleging that the patent may be infringed by our product candidates or proprietary technologies.

In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our owned and in-licensed issued patents or our pending applications, or that we or, if applicable, a licensor were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our owned and in-licensed patent applications or patents, which could require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to those owned by or in-licensed to us, we or, in the case of in-licensed technology, the licensor may have to participate in an interference or derivation proceeding declared by the USPTO to determine priority of invention in the United States. If we or one of our licensors is a party to an interference or derivation proceeding involving a U.S. patent application on inventions owned by or in-licensed to us, we may incur substantial costs, divert management's time and expend other resources, even if we are successful.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Litigation or interference proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application process and following the issuance of a patent. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In certain circumstances, even inadvertent noncompliance events may permanently and irrevocably jeopardize patent rights. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Any patents, if issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or the USPTO.

If we or one of our licensors initiate legal proceedings against a third-party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third-party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, inter partes review, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates.

Likewise, our current licensed patents covering our companion technologies, licensed from BWH and from Periphagen are expected to expire in 2036 and in 2069, respectively, without taking into account any possible patent term adjustments or extensions. Our earliest patents may expire before, or soon after, our first product achieves marketing approval in the United States or foreign jurisdictions. Upon the expiration of our current patents, we may lose the right to exclude others from practicing these inventions. The expiration of these patents could also have a similar material adverse effect on our business, results of operations, financial condition and prospects. We own pending patent applications covering our proprietary technologies or our product candidates that if issued as patents are expected to expire from 2037 through 2040, without taking into account any possible patent term adjustments or extensions. However, we cannot be assured that the USPTO or relevant foreign patent offices will grant any of these patent applications.

Changes in patent law in the U.S. and in foreign jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 16, 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. On March 16, 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO on or after March 16, 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be

insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of biopharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

We have limited intellectual property rights outside the United States. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of, and may require a compulsory license to, patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights generally. The initiation of proceedings by third parties to challenge the scope or validity of our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions such as patent term adjustments and/or extensions, may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984 Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

Risks Related to Our Common Stock and This Offering

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock in this offering.

Our stock price is likely to be volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the initial public offering price. The market price for our common stock may be influenced by many factors, including:

- the success of competitive products or technologies;
- results of clinical trials of our product candidates or those of our competitors;
- commencement or termination of collaboration, licensing or similar arrangements for our development programs;
- announcements by our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- developments or setbacks related to drugs that are co-administered with any of our product candidates, such as checkpoint inhibitors;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- expiration of market stand-off or lock-up agreements;
- changes in the structure of healthcare payment systems;

- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions and overall fluctuations in the financial markets in the United States and abroad; and
- the other factors described in this “Risk Factors” section.

In addition, COVID-19 has been spreading rapidly around the world since December 2019 and has negatively affected the stock market and investor sentiment. The price of our common stock may be disproportionately affected as investors may favor traditional profit-making industries and companies during the times of market uncertainty and instability.

An active trading market for our common stock may not develop, and you may not be able to resell your shares at or above the initial public offering price.

Prior to this offering, there has been no public market for shares of our common stock. Although we anticipate that our common stock will be approved for listing on The Nasdaq Global Select Market, or Nasdaq, an active trading market for our shares may never develop or be sustained following this offering. The initial public offering price of our common stock will be determined through negotiations between us and the underwriters. This initial public offering price may not be indicative of the market price of our common stock after this offering. In the absence of an active trading market for our common stock, investors may not be able to sell their common stock at or above the initial public offering price or at the time that they would like to sell.

Raising additional capital may cause dilution to our stockholders, including purchasers of common stock in this offering, restrict our operations or require us to relinquish rights to our technologies or current or future product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of private and public equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that may materially adversely affect your rights as a common stockholder. Debt financing, if available, would increase our fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, acquiring, selling or licensing intellectual property rights, making capital expenditures, declaring dividends, or other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to meet certain milestones in connection with debt financing and the failure to achieve such milestones by certain dates may force us to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us which could have a material adverse effect on our business, operating results and prospects.

If we raise funds through additional collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or current or future product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, scale back or discontinue the development and commercialization of one or more of our product candidates, delay our pursuit of potential in-licenses or acquisitions or grant rights to develop and market current or future product candidates that we would otherwise prefer to develop and market ourselves.

If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.

You will suffer immediate and substantial dilution in the net tangible book value of the common stock you purchase in this offering. Based on the initial public offering price of $8.00 per share, purchasers of common stock in this offering will experience immediate dilution of $4.95 per share in net tangible book value of the common stock. In addition, investors purchasing common stock in this offering will contribute 52.1% of the total amount invested by stockholders since inception but will only own 32.4% of the shares of common stock outstanding. In the past, we issued options and other securities to acquire common stock at prices significantly below the initial public offering price. To the extent these outstanding securities are ultimately exercised, investors purchasing common stock in this offering will sustain further dilution. See “Dilution” for a more detailed description of the dilution to new investors in the offering.

We are an "emerging growth company" as defined in the JOBS Act and a "smaller reporting company" as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act, and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies, which could make our common stock less attractive to investors and adversely affect the market price of our common stock.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) the last day of the fiscal year following the fifth anniversary of the date of the completion of this offering; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- providing only two years of audited financial statements in addition to any required unaudited interim financial statements and a correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. In this prospectus, we have not included all of the executive compensation-related information that would be required if we were not an emerging growth company.

We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of reduced reporting burdens in this prospectus. In particular, we have provided only two years of audited financial statements and have not included all of the executive compensation information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to use the extended transition period for new or revised accounting standards during the period in which we remain an emerging growth company; however, we may adopt certain new or revised accounting standards early.

We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company even after we no longer qualify an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies until the fiscal year following the determination that our voting and non-voting common stock held by non-affiliates is more than $250 million measured on the last business day of our second fiscal quarter, or our annual revenues are more than $100 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is more than $700 million measured on the last business day of our second fiscal quarter.

Although we are still evaluating the JOBS Act, we currently intend to take advantage of some, but not all, of the reduced regulatory and reporting requirements that will be available to us so long as we qualify as an "emerging growth company" and "smaller reporting company." We have elected to avail ourselves of this exemption and, therefore, we are not subject to the same new or revised accounting standards as other public companies that are

not emerging growth companies or smaller reporting company. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations. In addition, our independent registered public accounting firm will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting so long as we qualify as an "emerging growth company," which may increase the risk that material weaknesses or significant deficiencies in our internal control over financial reporting go undetected. Likewise, so long as we qualify as a "smaller reporting company" or an "emerging growth company," we may elect not to provide you with certain information, including certain financial information and certain information regarding compensation of our executive officers, that we would otherwise have been required to provide in filings we make with the SEC, which may make it more difficult for investors and securities analysts to evaluate our company. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile and may decline.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an "emerging growth company," we will incur significant legal, accounting and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which will require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act of 2002 and rules subsequently implemented by the SEC and Nasdaq have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas, such as "say on pay" and proxy access. Emerging growth companies may implement many of these requirements over a longer period and up to five years from the pricing of this offering. We intend to take advantage of these extended transition periods but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

Pursuant to Section 404, we will be required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are

functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. In additional, if we are not able to continue to meet these requirements, we may not be able to remain listed on Nasdaq.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lockup and other legal restrictions on resale discussed in this prospectus lapse, the trading price of our common stock could decline. Upon the closing of this offering, we will have outstanding a total of 27,798,454 shares of common stock. Of these shares, only the shares of common stock sold in this offering by us, plus any shares sold upon exercise of the underwriters' option to purchase additional shares, will be freely tradable without restriction in the public market immediately following this offering. In connection with this offering, our officers, directors and certain other stockholders, representing substantially all of our current stockholders, have agreed to be subject to a contractual lock-up with the underwriters, which will expire 180 days after the date of this prospectus.

The lock-up agreements contain important exceptions that govern their applicability. The underwriters, however, may, in their sole discretion, permit our officers, directors and other stockholders who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements.

In addition, shares of common stock that are reserved for future issuance under our 2021 Plan and our 2021 Employee Stock Purchase Plan, each of which became effective upon the effectiveness of the registration statement of which this prospectus forms a part, will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act of 1933, as amended, or the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

After this offering, the holders of 8,884,661 shares of our common stock will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the 180-day lock-up agreements described above. See "Description of Capital Stock—Registration Rights." Registration of these shares under the Securities Act would result in such shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

We have broad discretion in how we use the proceeds of this offering and may not use these proceeds effectively, which could affect our results of operations and cause our stock price to decline.

We will have considerable discretion in the application of the net proceeds of this offering. We intend to use the net proceeds from this offering to fund discovery and clinical development efforts as well as to further expand our manufacturing platform and capabilities, to grow our infrastructure to support our pipeline, and to fund new and ongoing research activities, working capital and other general corporate purposes, which may include funding for the hiring of additional personnel, capital expenditures and the costs of operating as a public company. As a result, investors will be relying upon management's judgment with only limited information about our specific intentions for the use of the balance of the net proceeds of this offering. We may use the net proceeds for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Our executive officers, directors, principal stockholders and their affiliates will continue to exercise significant influence over our company after this offering, which will limit your ability to influence corporate matters and could delay or prevent a change in corporate control.

Immediately following the completion of this offering, and disregarding any shares of common stock that they purchase in this offering, the existing holdings of our executive officers, directors, principal stockholders and their affiliates will represent beneficial ownership, in the aggregate, of approximately 48.5% of our outstanding common stock with Estuardo Aguilar-Cordova and Laura Aguilar (together, both directly and indirectly) beneficially owning approximately 28.7% of our outstanding common stock, and with entities and persons affiliated with PBM Capital beneficially owning approximately 21.7% of our outstanding common stock, assuming no exercise of the underwriters' option to acquire additional common stock in this offering, assuming we issue the number of shares of common stock as set forth on the cover page of this prospectus and without giving effect to any potential purchases by such persons in this offering, including pursuant to the directed share program relating to this offering. In addition, Diem Nguyen, who will join our Board of Directors prior to completion of this offering, is Chief Executive Officer of Xalud Therapeutics, Inc., which is majority-owned by PBM Capital. As a result, these stockholders, if they act together, will be able to influence our management and affairs and the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. These stockholders acquired their shares of common stock for substantially less than the price of the shares of common stock being acquired in this offering, and these stockholders may have interests with respect to their common stock that are different from those of investors in this offering. The concentration of voting power among these stockholders may have an adverse effect on the price of our common stock. In addition, this concentration of ownership might adversely affect the market price of our common stock by:

- delaying, deferring or preventing a change of control of us;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

See the section of this prospectus titled "Principal Stockholders" for more information regarding the ownership of our outstanding common stock by our executive officers, directors, principal stockholders and their affiliates.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control, which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws, which are to become effective upon the closing of this offering, will contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and

restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer, or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Our bylaws to be effective upon the consummation of this offering designate certain courts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our bylaws that will become effective upon the completion of this offering provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claim for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers, and employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein, or the Delaware Forum Provision. The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Our amended and restated bylaws further provide that, unless we consent in writing to the selection of an alternative forum, the United States District Court for the District of Massachusetts shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or the Federal Forum Provision, as our principal office is located in Needham, Massachusetts. In addition, our amended and restated bylaws that will become effective upon the completion of this offering will provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

The Delaware Forum Provision and the Federal Forum Provision in our amended and restated bylaws may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware or the Commonwealth of Massachusetts. Additionally, the forum selection clauses in our amended and restated bylaws may limit our stockholders' ability to bring a claim in a forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court were "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the United States District Court for the District of Massachusetts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock will rely in part on the research and reports that industry or financial analysts publish about us or our business. We may never obtain research coverage by industry or financial analysts. If no or few analysts commence coverage of us, the trading price of our stock would likely decrease. Even if we do obtain analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock may be volatile. The stock market in general, and Nasdaq and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In particular, the trading prices for pharmaceutical, biopharmaceutical and biotechnology companies have been highly volatile as a result of the COVID-19 pandemic. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

The number of shares of our common stock outstanding may increase substantially as a result of our November 2018 issuance of warrants to purchase up to an aggregate of 7,344,982 shares of common stock.

In connection with the November 13, 2018 issuance of Series B Preferred Stock, we issued warrants to purchase 3,672,491 shares of common stock for $6.81 per share to a purchaser of our Series B Preferred Stock which were immediately and remain fully exercisable upon issuance, or the Unconditional Series B Warrants. We also issued warrants for the purchase of up to an additional 3,672,491 shares of common for $6.81 per share, or the Conditional Series B Warrants. As amended on July 14, 2014, each of the Unconditional Series B Warrants and Conditional Series B Warrants expire in November 2025. The Conditional Series B Warrants are only exercisable in the event that we achieve certain financial conditions as follows: 918,123 shares vest upon a financing event effected through the sale of our equity securities to third parties resulting in at least $20,000,000 in gross proceeds, or a Financing Event, with a price per share of, or average market price (determined over a consecutive 10-day period) of, $12.47 per share; an additional 918,123 shares vest upon a Financing Event with a price per share of, or average market price of, $13.20 per share; an additional 918,122 shares vest upon a Financing Event with a price per share of, or average market price of, $13.94 per share; and an additional 918,122 shares vest upon a Financing Event with a price per share of, or average market price of, $14.68 per share. Based on the initial public offering price of $8.00 per share, the consummation of our initial public offering will not be a Financing Event that will result in the vesting of the Conditional Series B Warrants. The Unconditional Series B Warrants contain provisions allowing for cash and on a cashless exercise basis. The Conditional Series B Warrants are only exercisable in connection with the first to occur of (i) a sale of the Company or (ii) the Conditional Series B Warrants' expiration in November 2025. The Conditional Series B Warrants contain provisions allowing for cash and on a cashless exercise basis in connection with a sale event, and only on a cashless exercise basis in connection with the Conditional Series B Warrants' expiration in November 2025. The exercise of these warrants in full, assuming vesting in full of the Conditional Series B Warrants and no net exercise, would result in an additional 7,344,982 shares of common stock outstanding, resulting in substantial dilution to shareholders who hold our common stock. In addition, if the holders of these warrants, including PBM Capital, were to exercise such warrants in full, these holders could then have significant influence over the outcome of any shareholder vote, including the election of directors and the approval of mergers or other business combination transactions.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections entitled “Prospectus Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business,” contains express or implied forward-looking statements that are based on our management’s belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this prospectus include, but are not limited to, statements about:

- the timing and the success of preclinical studies and clinical trials of CAN-2409 and CAN-3110 and any other product candidates;
- the initiation of any clinical trials of CAN-2409 and CAN-3110 and any other product candidates;
- our need to raise additional funding before we can expect to generate any revenues from product sales;
- our ability to conduct successful clinical trials or obtain regulatory approval for CAN-2409 and CAN-3110 or any other product candidates that we may identify or develop;
- the ability of our research to generate and advance additional product candidates;
- the effect of the COVID-19 pandemic, including mitigation efforts and economic effects, on any of the foregoing or other aspects of our business operations;
- our ability to establish an adequate safety or efficacy profile for CAN-2409, CAN-3110 or any other product candidates that we may pursue;
- our ability to manufacture CAN-2409, CAN-3110 or any other product candidate in conformity with our specifications and the U.S. Food and Drug Administration’s requirements and to scale up manufacturing of our product candidates to commercial scale, if approved;
- the implementation of our strategic plans for our business, any product candidates we may develop and any companion diagnostics;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates any companion diagnostics;
- the rate and degree of market acceptance and clinical utility for any product candidates we may develop;
- our ability to use the proceeds of this offering in ways that increase the value of your investment;
- our expectations related to the use of proceeds from this offering, and estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- our ability to maintain and establish collaborations;
- the potential benefits with the continued existence of our license agreement with BWH;
- our financial performance;
- our ability to effectively manage our anticipated growth;
- developments relating to our competitors and our industry, including the impact of government regulation;
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals; and

other risks and uncertainties, including those listed under the section titled “Risk Factors.” In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “could”, “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “projects”, “potential,” “continue” or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the section titled “Risk Factors” and elsewhere in this prospectus. If one or more of these risks or uncertainties occur, or

if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. You should read this prospectus and the documents that we reference in this prospectus and have filed with the Securities and Exchange Commission as exhibits to the registration statement, of which this prospectus forms a part, completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

The forward-looking statements in this prospectus represent our views as of the date of this prospectus. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this prospectus.

This prospectus also contains estimates, projections and other information concerning our industry, our business, and the markets for our programs and product candidates. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from our own internal estimates and research as well as from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources. While we are not aware of any misstatements regarding any third-party information presented in this prospectus, their estimates, in particular, as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties, and are subject to change based on various factors, including those discussed under the section entitled “Risk Factors” and elsewhere in this prospectus. Some data are also based on our good faith estimates.

USE OF PROCEEDS

We estimate that our net proceeds from the sale of shares of our common stock in this offering will be approximately $63.2 million, or $73.2 million if the underwriters exercise in full their option to purchase additional shares, based on the initial public offering price of $8.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

We expect to use our net proceeds from this offering, together with our existing cash and cash equivalents, as follows:

- approximately $2.7 million to fund of patient enrollment for our Phase 3 clinical trial of CAN-2409 in high-grade glioma through the first quarter of 2023;
- approximately $15.6 million to fund the development, construction and qualification of our manufacturing facility and the development of commercial manufacturing capabilities at third-party contract manufacturers through the first quarter of 2023;
- approximately $3.7 million to fund our Phase 3 clinical trial of CAN-2409 for newly diagnosed prostate cancer in patients who have an intermediate- or high-risk for progression;
- approximately $8.3 million to fund the development of CAN-2409 and CAN-3110 in other clinical trials currently in process or contemplated; and
- the remaining proceeds for general corporate purposes, which may include the continued expansion of our HSV platform technology, hiring of additional personnel and consultants, capital expenditures and the costs of operating as a public company.

Based on our current plans, we believe that our existing cash and cash equivalents, together with the anticipated net proceeds to us from this offering, will enable us to fund our operations and capital expenditure requirements through the first quarter of 2023.

We may also use a portion of the net proceeds to in-license, acquire or invest in new businesses, technology or assets. Although we have no specific agreements, commitments or understandings with respect to any in-license or acquisition, we evaluate such opportunities and engage in related discussions with other companies from time to time.

Our expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above. The expected net proceeds from this offering will not be sufficient for us to fund any of our product candidates through regulatory approval, and we will need to raise substantial additional capital to complete the development and commercialization of our product candidates.

Due to the many inherent uncertainties in the development of our programs and product candidates, the amounts and timing of our actual expenditures and the extent of our preclinical and clinical development activities may vary significantly depending on numerous factors, including the progress of our research and development efforts, the status of and results from preclinical studies and our ongoing clinical trial or any clinical trials we may commence in the future, our ability to take advantage of expedited programs or to obtain regulatory approval for our product candidates and any other product candidates we may identify and pursue, the timing and costs associated with the manufacture and supply of product candidates and any other product candidates we may identify and pursue for clinical development or commercialization, and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term and long-term, investment-grade, interest-bearing instruments and U.S. government securities. We cannot predict whether the proceeds invested will yield a favorable return. Our

management will retain broad discretion in the application of the net proceeds we receive from our initial public offering, and investors will be relying on the judgment of our management regarding the application of the net proceeds.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. We do not intend to pay cash dividends to our stockholders in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions, and other factors that our board of directors may deem relevant. Investors should not purchase our common stock with the expectation of receiving cash dividends.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and our capitalization as of March 31, 2021:

- on an actual basis;
- on a pro forma basis to give effect to:
  - the automatic conversion of 17,187,576 outstanding shares of our redeemable convertible preferred stock into an aggregate of 7,066,565 shares of our common stock upon the closing of this offering; and
  - the filing and effectiveness of our amended and restated certificate of incorporation; and
- on a pro forma as adjusted basis to give further effect to our issuance and sale of 9,000,000 shares of our common stock in this offering at the initial public offering price of $8.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us and the issuance of 58,754 shares of common stock pursuant to warrant exercises subsequent to March 31, 2021.

The following table should be read together with “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” “Description of Capital Stock,” and the consolidated financial statements and related notes appearing elsewhere in this prospectus.

	AT MARCH 31, 2021		
	ACTUAL	PRO FORMA	PRO FORMA AS ADJUSTED
	(In thousands, except share and per share data)		
Cash and cash equivalents	$ 29,152	$ 29,152	$ 92,484
Redeemable convertible preferred stock, $0.01 par value; 17,187,676 shares authorized, issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	49,060	—	—
Stockholders’ Equity (Deficit)			
Preferred stock, $0.01 par value; 17,187,676 shares authorized, issued or outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	—	—	—
Common stock, $0.01 par value; 75,000,000 shares authorized, 11,673,135 shares issued and outstanding, actual; 75,000,000 shares authorized, 18,798,454 shares issued and outstanding, pro forma; 150,000,000 shares authorized, 27,798,454 shares issued and outstanding, pro forma as adjusted	117	187	278
Additional paid-in capital	21,035	70,025	133,094
Accumulated deficit	(48,649)	(48,649)	(48,649)
Total stockholders’ equity (deficit)	(27,497)	21,563	84,723
Total capitalization	$ 21,563	$ 21,563	$ 84,723

The information set forth in the table excludes:

- 4,079,006 shares of our common stock issuable upon the exercise of stock options outstanding as of March 31, 2021 under our 2015 Stock Plan, or the 2015 Plan, at a weighted average exercise price of $1.60 per share;
- 78,307 shares of our common stock reserved and available for future issuance under the 2015 Plan, as of

March 31, 2021, which will cease to be available for issuance at the time that our 2021 Stock Option and Incentive Plan, or the 2021 Plan, becomes effective;

- 7,524,262 shares of our common stock reserved and available for future issuance upon exercise of the outstanding warrants, as of June 30, 2021 at a weighted average exercise price of $6.69 per share;
- 2,054,000 shares of our common stock that will become available for future issuance under the 2021 Plan, which will become effective in connection with the completion of this offering; and
- 293,000 shares of common stock that will become available for future issuance under our 2021 Employee Stock Purchase Plan, or ESPP, which will become effective in connection with the completion of this offering.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock after this offering.

Our historical net tangible book value (deficit) as of March 31, 2021 was $(28.4) million, or $(2.44) per share of our common stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets less our total liabilities and preferred stock, which is not included within our stockholders' (deficit) equity. Historical net tangible book value per share represents historical net tangible book value (deficit) divided by the 11,673,135 shares of our common stock outstanding as of March 31, 2021.

Our pro forma net tangible book value as of March 31, 2021 was $20.6 million, or $1.10 per share of our common stock. Pro forma net tangible book value represents the amount of our total tangible assets less our total liabilities, after giving effect to the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into an aggregate of 7,066,565 shares of our common stock upon the closing of this offering. Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of shares outstanding as of March 31, 2021 after giving effect to the pro forma adjustment described above.

After giving further effect to our issuance and sale of 9,000,000 shares of our common stock in this offering at the initial public offering price of $8.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us and the issuance of 58,754 shares of common stock subsequent to March 31, 2021, our pro forma as adjusted net tangible book value as of March 31, 2021 would have been $84.7 million, or $3.05 per share. This represents an immediate increase in pro forma as adjusted net tangible book value per share of $1.95 to existing stockholders and immediate dilution of $4.95 per share in pro forma as adjusted net tangible book value per share to new investors purchasing common stock in this offering. Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis:

Initial public offering price per share		$8.00
Historical net tangible book value (deficit) per share as of March 31, 2021	$(2.44)	
Increase per share attributable to the pro forma adjustment described above	3.54	
Pro forma net tangible book value per share as of March 31, 2021	1.10	
Increase in pro forma as adjusted net tangible book value per share attributable to new investors purchasing common stock in this offering	1.95	
Pro forma as adjusted net tangible book value per share after this offering		3.05
Dilution per share to new investors purchasing common stock in this offering		$4.95

If the underwriters exercise their option to purchase 1,350,000 additional shares in full, our pro forma as adjusted net tangible book value per share after this offering would be $3.25 and the dilution in pro forma as adjusted net tangible book value per share to new investors purchasing common stock in this offering, based on the initial public offering price of $8.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. If any shares are issued upon exercise of outstanding options, you will experience further dilution.

The following table summarizes on the pro forma as adjusted basis described above, the differences between the number of shares of common stock purchased from us on an as converted to common stock basis, the total consideration paid to us and the average price per share paid by existing stockholders and by new investors purchasing shares of common stock in this offering. The calculation below is based on the initial public offering price of $8.00 per share, before deducting underwriting discounts and commissions and estimated offering expenses payable by us. As the table shows, new investors purchasing common stock in this offering will pay an average price per share substantially higher than our existing stockholders paid.

	SHARES PURCHASED		TOTAL CONSIDERATION		AVERAGE PRICE PER SHARE
	NUMBER	PERCENT	AMOUNT	PERCENTAGE	
Existing stockholders	18,798,454	67.6%	$ 66,093,658	47.9%	$ 3.52
New investors	9,000,000	32.4	72,000,000	52.1	$ 8.00
Total	27,798,454	100.0%	$138,093,658	$ 100.0%	

The table above assumes no exercise of the underwriters' option to purchase additional shares in this offering. If the underwriters' option to purchase additional shares is exercised in full, the number of shares of our common stock held by existing stockholders would be reduced to 64.5% of the total number of shares of our common stock outstanding after this offering, and the number of shares of common stock held by new investors participating in this offering would be increased to 35.5% of the total number of shares of our common stock outstanding after this offering.

The number of shares of our common stock to be outstanding after this offering is based on 18,798,454 shares of common stock outstanding as of June 30, 2021, which includes 11,673,135 shares of our common stock outstanding as of March 31, 2021, plus the conversion of preferred stock into 7,066,565 shares of common stock and 58,754 shares of common stock issued subsequent to March 31, 2021 through June 30, 2021, and excludes:

- 4,079,006 shares of our common stock issuable upon the exercise of stock options outstanding as of March 31, 2021 under our 2015 Stock Plan, or the 2015 Plan, at a weighted average exercise price of $1.60 per share;
- 78,307 shares of our common stock reserved and available for future issuance under the 2015 Plan, as of March 31, 2021, which will cease to be available for issuance at the time that our 2021 Stock Option and Incentive Plan, or the 2021 Plan, becomes effective;
- 7,524,262 shares of our common stock reserved and available for future issuance upon exercise of the outstanding warrants as of June 30, 2021, at a weighted average exercise price of $6.69 per share;
- 2,054,000 shares of our common stock that will become available for future issuance under the 2021 Plan, which will become effective in connection with the completion of this offering; and
- 293,000 shares of common stock that will become available for future issuance under our 2021 Employee Stock Purchase Plan, or ESPP, which will become effective in connection with the completion of this offering.

To the extent that outstanding options are exercised or shares are issued under our 2021 Plan, you will experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities may result in further dilution to our stockholders.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes and other financial information included elsewhere in this prospectus. Some of the information contained in this discussion and analysis contains forward-looking statements that involve risks and uncertainties. You should review the section titled "Risk factors" in this prospectus for a discussion of important factors that could cause actual results to differ materially from the results described below.

Overview

We are a late clinical stage biopharmaceutical company focused on helping patients fight cancer with oncolytic viral immunotherapies. Our engineered viruses are designed to induce immunogenic death through direct viral-mediated cytotoxicity in cancer cells, thus releasing tumor neo-antigens and creating a pro-inflammatory microenvironment at the site of injection. Our approach combines an in-depth knowledge of viral immunotherapy with extensive clinical experience across a wide range of indications. Based on the broad range of data that we have generated from our preclinical models and clinical trials using our approach, we have observed what we believe to be systemic immune response against locally injected tumors and their distant metastases. We have established two oncolytic viral immunotherapy platforms based on novel, genetically modified adenovirus and herpes simplex virus (HSV) constructs. In our clinical results to date from CAN-2409, our lead product from our adenovirus platform, and CAN-3110, our lead product candidate from our HSV platform, we have observed that these candidates may have the potential to address significant unmet patient need and improve clinical outcomes in novel indications across broader patient populations.

Since our formation, we have devoted substantially all our resources to developing our oncolytic viral immunotherapy and our adenovirus platform, conducting research and development activities, including product candidate development, recruiting skilled personnel, establishing our intellectual property portfolio, raising capital and providing general and administrative support for these operations. We have financed our operations primarily through proceeds from the sale of convertible notes, common stock and our convertible preferred stock. As of June 30, 2021, we have raised approximately $81.3 million through a combination of convertible notes, common stock, convertible preferred stock financings, and government grants.

We were incorporated under the laws of the State of Delaware in June 2003. Our principal executive office is located at 117 Kendrick St, Suite 450, Needham, Massachusetts 02494. On November 30, 2020, we formally changed our name to Candel Therapeutics, Inc., previously Advantagene, Inc. Since our formation, we have incurred significant operating losses and have not generated any revenue from the sale of products. Our ability to generate any product revenue or product revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of one or more of our product candidates. Our net losses were $8.2 million, $17.7 million and $4.5 million for the years ended December 31, 2019 and 2020, and the three months ended March 31, 2021, respectively. As of March 31, 2021, we had an accumulated deficit of $48.6 million.

We will not generate revenue from product sales unless and until we successfully complete clinical development, obtain regulatory approval for, and successfully commercialize our product candidates. The lengthy process of securing marketing approvals for new drugs requires the expenditure of substantial resources. Any significant delay or failure to obtain regulatory approvals would materially adversely affect our product candidates development efforts and our business overall. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing, manufacturing and distribution activities. In addition, following the closing of this offering, we expect to incur significant additional costs associated with operating as a public company. We anticipate that our expenses will increase significantly as we:

- advance the development of our product candidate pipeline;
- initiate and continue research and preclinical and clinical development of potential new product candidates;
- maintain, expand and protect our intellectual property portfolio;
- acquire or in-license additional product candidates and technologies;
- expand our infrastructure and facilities to accommodate our growing employee base and ongoing development activities;

- establish agreements with contract research organizations, or CROs, and third-party contract manufacturing organizations, or CMOs, in connection with our preclinical studies and clinical trials;
- develop the manufacturing process and capabilities for future clinical trials and commercialization;
- manufacture larger quantities of our product candidates for clinical development and potential commercialization;
- seek marketing approvals for our product candidates that successfully complete clinical trials, if any;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval; and
- add operational, financial and management information systems and personnel, including personnel to support our research and development programs, any future commercialization efforts and our transition to operating as a public company following the completion of this offering.

As a result of these anticipated expenditures, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time, if ever, as we can generate significant revenue from product sales, we expect to finance our cash needs through a combination of public or private equity or debt financings and other sources, which may include collaborations, strategic alliances and licensing arrangements with third parties. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. Our inability to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We cannot assure you that we will ever generate sufficient revenue to achieve profitability.

Because of the numerous risks and uncertainties associated with the development of therapeutics, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we can generate revenue from product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be required to raise additional capital on terms that are unfavorable to us or we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

Collaborations

We are a party to a number of license and collaboration agreements under which we license patents, patent applications and other intellectual property to and from third parties.

Periphagen. On December 9, 2019, we entered into a series of agreements, including an exclusive license agreement, a novation agreement, an equipment purchase agreement and an intellectual property assignment agreement, collectively the Periphagen Agreements, with Periphagen, whereby we acquired certain assets and licensed certain rights (including specified patent rights and know-how, or the Licensed IP Rights) of Periphagen, primarily consisting of exclusive rights to their technology platform and a portfolio of pre-clinical, development stage virus vectors. The primary classes of assets are HSV-derived assets expressing neurotrophin-3 (or NT-3 Assets) and other HSV-derived assets (Gene Transfer Neuro-Assets). Under the license agreement, Periphagen granted us a worldwide exclusive license with the right to grant sublicenses through multiple tiers under the Licensed IP Rights to conduct research and to develop, make, have made, use, have used, offer for sale, have sold, export and import products incorporating the Licensed IP Rights in all fields of use except the treatment, diagnosis, and prevention of nononcologic skin diseases and conditions (including use as an aesthetic).

BWH. On January 20, 2018, we entered into an exclusive option agreement, or the Option Agreement, with BWH. Pursuant to the Option Agreement, we obtained the exclusive right from BWH to negotiate a world-wide, royalty-bearing license to develop and commercialize products covered by certain BWH patents, including those patents covering CAN-3110, in the field of gene therapy and oncolytic vector therapy for the treatment or prevention of cancerous tumors in humans or animals, as such field is further detailed in the Option Agreement, or the Licensed Field. In consideration for BWH's granting of the exclusive option, we paid BWH a non-refundable fee of $40,000.

Under the Option Agreement, we were required to use reasonable efforts to enter into a clinical trial agreement with BWH. We entered into such clinical trial agreement with BWH, or the BWH Clinical Trial Agreement, on June 19, 2018. Under the BWH Clinical Trial Agreement, we have committed to remitting financial support for the performance of a specified Phase 1 clinical trial by BWH pursuant to a protocol summary contained in the Option Agreement.

On September 15, 2020, we exercised our option and entered into an exclusive patent license agreement with BWH, or the BWH License Agreement. Under the BWH License Agreement, BWH granted to us (a) an exclusive, royalty-bearing license under certain of BWH's patents to make, have made, use, have used, sell and have sold certain products covered by such licensed patents, or the Licensed Products and otherwise practice processes covered by such licensed patents, or Licensed Processes; and (b) a non-exclusive, royalty-bearing license under certain other of BWH's patents to make, have made, use, have used, sell and have sold Licensed Products, but not to sell or have sold Licensed Processes. The foregoing rights are sublicensable, subject to sublicensing terms set forth in the BWH License Agreement. In connection with executing the BWH License Agreement, we paid a license issue fee and also agreed to reimburse BWH for all reasonable fees and expenses BWH had incurred and will incur for the preparation, filing, prosecution and maintenance of the licensed patent rights.

Ventagen. On March 1, 2014, we entered into an exclusive license agreement, or the Ventagen Agreement, with Ventagen, a related party. The Ventagen Agreement provides Ventagen an exclusive license, with rights to grant sublicense (subject to certain terms and conditions) under any worldwide patent rights and know-how owned or controlled by us during the term of the Ventagen Agreement which cover applicable technology utilizing the delivery method of the herpes derived TK protein to tumors or other tissues via a viral vector (as further specified therein), to research, use, have used, import, have imported, export, have exported, offer for sale, have sold, sell, distribute and market certain products for the prevention or treatment of cancer in humans and any use in animals (or the Field of Use), or the Licensed Products, for commercial sale and distribution within Mexico, Belize, Guatemala, Honduras, El Salvador, Costa Rica, Nicaragua, Panama, Colombia and Bolivia. Ventagen is 49.5% owned by certain of our shareholders.

As of March 31, 2021, we had cash and cash equivalents of $29.2 million. We believe the existing cash and cash equivalents on hand as of March 31, 2021, together with the anticipated net proceeds from this offering, will enable us to fund our operating expenses and capital expenditure requirements through the first quarter of 2023. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See "—Liquidity and capital resources."

Impact of COVID-19 Pandemic

In March 2020, the World Health Organization declared the outbreak of the novel coronavirus, or COVID-19, a global pandemic, or the COVID-19 pandemic, which continues to spread throughout the United States and worldwide. The ultimate extent of the impact of the COVID-19 pandemic on our business, financial condition and results of operations is highly uncertain and will depend on future developments that cannot be predicted, including new information that may emerge concerning the severity of COVID-19 and actions taken by government authorities and businesses to contain or prevent the further spread of COVID-19. For instance, a recurrence or continuation of COVID-19 cases could cause a more widespread or severe impact on commercial activity depending on where infection rates are highest. If we or any of the third parties with whom we engage were to experience any additional shutdowns or other prolonged business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially or negatively affected, which could have a material adverse impact on our business, results of operations and financial condition.

To date, we have been carefully monitoring the COVID-19 pandemic and its potential impact on our business and have taken important steps to help ensure the safety of our employees and their families and to reduce the spread of COVID-19. We have established a work-from-home policy for all employees, other than those performing or supporting business-critical operations, such as certain members of our laboratory and facilities staff. For those employees, we have implemented stringent safety measures designed to comply with applicable federal, state and local guidelines instituted in response to the COVID-19 pandemic. We have also maintained efficient communication with our partners and clinical sites as the COVID-19 pandemic has progressed. We have taken these precautionary steps while maintaining business continuity so that we can continue to progress our programs. While we have experienced some delays in enrollment and site closures at certain of our third-party clinical trial sites, these delays have not had a material impact on our development timelines for our product candidates. We will continue to monitor developments as we address the disruptions and uncertainties relating to the COVID-19 pandemic. See "Risk Factors" for a discussion of the potential adverse impact of the COVID-19 pandemic on our business, financial condition and results of operations.

Components of our results of operations

Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from sales of products in the foreseeable future. We are recognizing as research and development service revenue $1.0 million that we received in 2014 and 2015 from Ventagen for an exclusive license to develop products for commercial sale and development within certain countries. The $1.0 million is being recognized as revenue over the period during which we provide services under the license agreement.

Operating Expenses

Our operating expenses since inception have consisted solely of research and development costs and general and administrative costs.

Research and development expenses

Research and development expenses consist primarily of costs incurred for our product development activities for our two primary drug candidates, CAN-2409 and CAN-3110. We expense research and development costs as incurred. These include the following:

- employee-related costs, including salaries, benefits and stock-based compensation expense, for personnel engaged in research, development and clinical management functions;
- expenses incurred under agreements with third party clinical sites for the treatment and follow-up for patients enrolled in our clinical trials;
- the cost of acquiring and manufacturing preclinical study materials, including manufacturing registration and validation batches;
- acquisition of in-process research and development assets that have no alternative future use;
- payments made under third-party licensing agreements;
- costs incurred to develop the manufacturing process and capabilities for future clinical trials and commercialization. Our clinical trial material for use in our existing clinical trials was manufactured in prior years;
- costs related to compliance with quality and regulatory requirements;
- costs of outside consultants, primarily related to regulatory; and
- facility-related expenses, which include direct depreciation costs and expenses for rent and maintenance of facilities and insurance, and other operating costs if specifically identifiable to research and development activities.

We expect that our research and development expenses will continue to increase substantially for the foreseeable future and will comprise a larger percentage of our total expenses as we complete our clinical trials and commence additional clinical trials, continue to discover and develop additional product candidates and develop and scale our in-house manufacturing capabilities. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to increased scale and duration of later stage clinical trials.

We cannot determine with certainty the duration and costs of future clinical trials of CAN-2409 and CAN-3110 or any other product candidate we may develop or if, when, or to what extent we will generate revenue from the commercialization and sale of any product candidate for which we obtain marketing approval. At this time, we cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the clinical development of, or obtain regulatory approval for, any of our current or future product candidates. The duration, costs, and timing of clinical trials and development of CAN-2409 and CAN-3110 and any other product candidate we may develop will depend on a variety of factors, including:

- the scope, rate of progress, expense and results of clinical trials;
- our successful enrollment in and completion of clinical trials, including our ability to generate positive data from any such trials;
- our ability to add and retain key research and development personnel;

- the actual probability of success for our product candidates, including their safety and efficacy, early clinical data, competition, manufacturing capability, and commercial viability;
- significant and changing government regulation and regulatory guidance;
- the timing and receipt of any marketing approvals;
- the progress of the development efforts of parties with whom we may enter into collaboration agreements, and the terms and timing of any additional collaboration agreements, license or other arrangement, including the timing of any payments thereunder;
- our ability to complete development, construction and qualification of manufacturing facility;
- costs related to manufacturing of our product candidates or to account for any future changes in our manufacturing plans;
- our ability to successfully commercialize our product candidates, if and when approved;
- raising additional funds necessary to complete clinical development of our product candidates;
- our ability to obtain and maintain third-party insurance coverage and adequate reimbursement for our product candidates, if and when approved;
- the acceptance of our product candidates, if approved, by patients, the medical community and third-party payors;
- effectively competing with other products if our product candidates are approved;
- the impact of any business interruptions to our operations, including the timing and enrollment of patients in our planned clinical trials, or to those of our manufacturers, suppliers, or other vendors resulting from the COVID-19 pandemic or similar public health crisis;
- our ability to maintain a continued acceptable safety profile for our therapies following approval;
- our ability to obtain and maintain patents, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates, both in the United States and internationally; and
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

A change in the outcome of any of these variables with respect to the development of a product candidate could significantly change the costs and timing associated with the development of that product candidate. We may never succeed in obtaining regulatory approval for any of our product candidates.

General and administrative expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive, finance, business development, and administrative functions. General and administrative expenses also include legal fees relating to intellectual property and corporate matters; professional fees for accounting, auditing, tax and consulting services; insurance costs; travel expenses; and facility-related expenses, which include direct depreciation costs and expenses for rent and maintenance of facilities, and other operating costs that are not specifically attributable to research and development activities.

We expect that our general and administrative expenses will increase in the future as we increase our personnel headcount to support our continued clinical development and manufacturing activities. Following this offering, we also expect to incur increased expenses associated with being a public company, including costs of accounting, audit, legal, regulatory, and tax-related services associated with maintaining compliance with exchange listing and Securities and Exchange Commission, or SEC, requirements; director and officer insurance costs; and investor and public relations costs.

Grant income

Grant income consists of amounts received under a grant from the National Institute of Health for development of CAN-2409 for use as a therapy for pancreatic cancer.

Interest, dividend, and investment income

Interest, dividend and investment income consists of amounts earned on investment of cash equivalents and short-term investments.

Change in fair value of warrant liability

We have issued two warrants to PBM ADV Holdings, LLC, one of our Series B preferred stockholders, to purchase up to 7,344,982 shares of our common stock with an exercise price of $6.81 per share, and a warrant to the NC Incorporated Ohio Trust, an irrevocable trust funded by us, to purchase 162,740 shares of our common stock, $0.01 par value, at an exercise price of $1.46 per share, subject to adjustments as specified in the warrant agreement. Certain of those warrants are recorded as a liability on our balance sheet. The warrants recorded as a liability are remeasured to their fair value at each reporting date with changes in the fair value recognized as a component of other income (expense), net in the statements of operations and comprehensive loss. We will continue to recognize changes in the fair value of the warrant liability until the warrants are exercised, expire or qualify for equity classification. The fair value of the warrant liability is determined based on significant inputs not observable in the market. The fair value of the warrant liability uses various valuation methods, including the Monte Carlo method, the option-pricing method, probability-weighted expected return and the hybrid method, all of which incorporate assumptions and estimates, to value the common stock warrants. The hybrid method is often used when a company is expecting a liquidity event in the near future and is a combination of the option-pricing and probability-weighted expected return methods. Estimates and assumptions impacting the fair value measurement include the fair value per share of the underlying shares of common stock, risk-free interest rate, expected dividend yield, expected volatility of the price of the underlying preferred stock, and the remaining contractual term of the warrants. Therefore, the fair value may not be appropriately captured by simple models.

Income taxes

Since our inception, we have generated cumulative federal and state net operating loss and research and development credit carryforwards for which we have not recorded any net tax benefit due to uncertainty around utilizing these tax attributes within their respective carryforward periods.

As of December 31, 2020, we had federal net operating loss carryforwards, or NOLs, of approximately $28.5 million and state NOLs of approximately $27.6 million which may be available to offset future taxable income. Our federal NOLs include $8.8 million available to reduce future taxable income through 2028 and approximately $19.7 million of NOLs that do not expire and are available to reduce future taxable income indefinitely. The state NOLs are available to offset future taxable income through 2032. As of December 31, 2019, we also had federal and state research and development tax credit carryforwards of $1.2 million and $0.7 million, respectively, which are available to offset federal and state tax liabilities through 2036 and 2028, respectively.

Realization of future tax benefits is dependent on many factors, including our ability to generate taxable income within the NOL period. Our management has evaluated the positive and negative evidence bearing upon the realizability of our deferred tax assets, which are comprised principally of net operating loss carryforwards and certain tax credits. Management has considered our history of cumulative net losses incurred since inception, as well as our lack of product revenue since inception, and has determined that it is more likely than not that we will not realize the benefits of its deferred tax assets. As a result, a full valuation allowance has been established at December 31, 2020.

NOL and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50%, as provided under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, as well as under similar state provisions. These ownership changes may limit the amount of NOLs that can be utilized annually to offset future taxable income. In general, an ownership change, as defined under Section 382 of the Code, or Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50% over a three-year period. We have completed several financings and not yet determined if such a limitation would be placed against our NOL. We will make such a determination prior to the utilization of any NOL.

Results of operations

The following table summarizes our results of operations for the years ended December 31, 2019 and 2020 and the three months ended March 31, 2020 and 2021 (in thousands):

	YEAR ENDED DECEMBER 31,		INCREASE/	THREE MONTHS ENDED MARCH 31,		INCREASE/
	2019	2020	(DECREASE)	2020	2021	(DECREASE)
Research and development service revenue	$ 125	$ 125	$ —	$ 31	$ 31	$ —
Operating expenses:						
Research and development	6,607	8,754	2,147	1,621	2,753	1,132
General and administrative	2,555	5,181	2,626	728	1,935	1,207
Total operating expenses	9,162	13,935	4,773	2,349	4,688	2,339
Loss from operations	(9,037)	(13,810)	4,773	(2,318)	(4,657)	2,339
Grant income	571	624	(53)	163	191	(28)
Interest, dividend and investment income, net	1,070	111	959	(72)	(12)	(60)
Change in fair value of warrant liability	(844)	(4,605)	3,761	455	—	455
Net loss	$ (8,240)	$ (17,680)	$ 9,440	$ (1,772)	$ (4,478)	$ 2,706

Comparison of the Years End December 31, 2019 and 2020

Revenue

We had research and development service revenue of $125,000 for each of the years ended December 31, 2019 and 2020. This represents the recognition as research and development service revenue of a portion of the $1.0 million that we received in 2014 and 2015 from Ventagen, a related party, which is being recognized over the period during which we provide the services.

Research and development expenses

The following table summarizes our research and development expenses for the years ended December 31, 2019 and 2020 (in thousands):

	YEAR ENDED DECEMBER 31,		INCREASE
	2019	2020	(DECREASE)
Employee - related	$ 2,781	$ 5,269	$ 2,488
Clinical development costs	1,822	2,156	334
In process research and development	1,263	—	(1,263)
Occupancy	551	812	261
Other	190	517	327
	$ 6,607	$ 8,754	$ 2,147

Research and development expenses for the year ended December 31, 2019 were $6.6 million, compared with $8.8 million for the year ended December 31, 2020 and consisted primarily of $2.8 million and $5.3 million, respectively, of employee-related costs, including $138,000 and $847,000, respectively, of non-cash stock

compensation expense, $1.8 million and $2.2 million, respectively, of clinical development costs related to our clinical trial sites and the cost of treating and following up on patients in our clinical trials and $551,000 and $812,000, respectively, of facility and occupancy related costs. The increase of $2.1 million for the year ended December 31, 2020, was primarily due to an increase of $2.5 million in employee-related costs, an increase of $334,000 in clinical development costs, an increase of $261,000 in occupancy and facility costs and an increase of $327,000 in other research costs. These increases were partially offset by the $1.3 million charge for in-process research and development recorded in 2019 related to the acquisition of Periphagen. The $2.5 million increase in employee-related costs was primarily due to the increase of $709,000 in non-cash compensation expense and an increase in the research and development headcount. In the year ended December 31, 2019, we recorded a charge of $1.3 million for the fair value of the technology platform, intellectual property and virus vectors acquired from Periphagen as the assets represent in-process research and development with no alternative future use.

General and administrative expenses

The following table summarizes our general and administrative expenses for the years ended December 31, 2019 and 2020 (in thousands):

	YEAR ENDED DECEMBER 31,		INCREASE (DECREASE)
	2019	2020	
Employee-related	$ 1,240	$ 2,656	$ 1,416
Professional and consulting	825	2,004	1,179
Occupancy	204	256	52
Other	286	265	(21)
	$ 2,555	$ 5,181	$ 2,626

General and administrative expenses were $2.6 million for the year ended December 31, 2019 compared with $5.2 million for the year ended December 31, 2020 and consisted primarily of $1.2 million and $2.7 million, respectively, of employee-related costs, including $262,000 and $1.3 million of non-cash stock compensation expense, $825,000 and $2.0 million, respectively, of professional and consulting fees and $204,000 and $256,000, respectively, of facility and other occupancy related costs. The increase of $2.6 million was primarily due to an increase of $1.4 million in employee – related costs as we increased our general and administrative headcount to manage growth, including an increase of $1.0 million in non-cash compensation expense, and an increase of $1.2 million in professional and consulting fees. The increase in professional and consulting fees is primarily due to an increase in fees paid to personnel search firms, public relations consultants, commercial market research firms and legal and accounting firms.

Grant income

Grant income was $571,000 for the year ended December 31, 2019 compared with $624,000 for the year ended December 31, 2020. The grant represents amounts received under a grant from the National Institutes of Health for development of CAN-2409 for use as a therapy for pancreatic cancer.

Interest, dividend and investment income, net

Interest, dividend and investment income, net was $1.1 million for the year ended December 31, 2019 compared with $111,000 for the year ended December 31, 2020 and represents the earnings on our cash equivalents and short-term investments. The decrease is primarily due to a decrease in the yields earned on cash equivalents and short term investments as well as a decrease in funds available for investment.

Change in fair value of warrant liability

The change in fair value of our warrant liability was an increase of $844,000 for the year ended December 31, 2019 compared to an increase of $4.6 million for the year ended December 31, 2020.

Comparison of three months ended March 31, 2020 and 2021

Revenue

We had research and development service revenue of $31,000 for each of the three month periods ended March 31, 2020 and 2021. This represents the recognition as research and development service revenue of a portion of the

$1.0 million that we received in 2014 and 2015 from Ventagen, a related party, which is being recognized over the period during which we provide the services.

Research and development expenses

The following table summarizes our research and development expenses for the three months ended March 31, 2020 and 2021 (in thousands):

	THREE MONTHS ENDED MARCH 31,		INCREASE (DECREASE)
	2020	2021	
Employee-related	$ 888	$ 1,495	$ 607
Clinical development costs	506	586	80
Search fees	—	202	202
Occupancy	170	129	(41)
Other	57	341	284
	$ 1,621	$ 2,753	$ 1,132

Research and development expenses for the three months ended March 31, 2020 were $1.6 million, compared with $2.8 million for the three months ended March 31, 2021 and consisted primarily of $888,000 and $1.5 million, respectively, of employee-related costs, including $(85,000) and $115,000, respectively, of non-cash stock compensation expense, $506,000 and $586,000, respectively, of clinical development costs related to our clinical trial sites and the cost of treating and following up on patients in our clinical trials, $0 and $202,000 respectively, of fees paid to employee search firms and $170,000 and $129,000, respectively, of facility and occupancy related costs. The increase of $1.1 million for the three months ended March 31, 2021, was primarily due to an increase of $607,000 in employee-related costs, an increase of $80,000 in clinical development costs, an increase of $202,000 in employee search costs, a decrease of $41,000 in occupancy and facility costs, and an increase of $284,000 in other research costs consisting primarily of increases in manufacturing and regulatory expenses. The $607,000 increase in employee-related costs was primarily due to the increase of $200,000 in non-cash compensation expense and an increase in the research and development headcount.

General and administrative expenses

The following table summarizes our general and administrative expenses for the three months ended March 31, 2020 and 2021 (in thousands):

	THREE MONTHS ENDED MARCH 31,		INCREASE (DECREASE)
	2020	2021	
Employee-related	$ 413	$ 1,031	$ 618
Professional and consulting	180	749	569
Occupancy	63	63	—
Other	72	92	20
	$ 728	$ 1,935	$ 1,207

General and administrative expenses were $728,000 for the three months ended March 31, 2020 compared with $1.9 million for the three months ended March 31, 2021 and consisted primarily of $413,000 and $1.0 million, respectively, of employee-related costs, including $53,000 and $316,000, respectively, of non-cash stock compensation expense, $180,000 and $749,000, respectively, of professional and consulting fees and $63,000 and $63,000, respectively, of facility and other occupancy related costs. The increase of $1.2 million was primarily due to an increase of $618,000 in employee – related costs as we increased our general and administrative headcount to manage growth, including an increase of $263,000 in non-cash compensation expense, and an increase of $569,000 in professional and consulting fees. The increase in professional and consulting fees is

primarily due to an increase in fees paid to personnel search firms, public relations consultants, commercial market research firms, legal firms and accounting firms.

Grant income

Grant income was $163,000 for the three months ended March 31, 2020 compared with $191,000 for the three months ended March 31, 2021. The grant represents amounts received under a grant from the National Institutes of Health for development of CAN-2409 for use as a therapy for pancreatic cancer.

Interest, dividend and investment income, net

Interest, dividend and investment income, net was an expense of $72,000 for the three months ended March 31, 2020 compared with an expense of $12,000 for the three months ended March 31, 2021 and represents the earnings on our cash equivalents and short-term investments net of interest expense on our outstanding debt obligations. The decrease is primarily due to a decrease in the yields earned on cash equivalents and short term investments, a decrease in funds available for investment and a decrease in outstanding debt obligations.

Change in fair value of warrant liability

The change in fair value of our warrant liability was a decrease in value of $455,000 for the three months ended March 31, 2020. There was no change in the warrant liability for the three months ended March 31, 2021. The decrease in the warrant liability for the three months ended March 31, 2020 was due to the decline in the stock market in the first quarter 2020.

Liquidity and capital resources

Since our inception, we have not generated any revenue from product sales and have incurred significant operating losses. We expect to continue to incur significant expenses and operating losses for the foreseeable future as we advance the clinical development of our product candidates. We expect that our research and development and general and administrative costs will continue to increase significantly, including in connection with conducting clinical trials for our product candidates, developing our manufacturing capabilities and building and qualifying our manufacturing facility to support clinical trials and commercialization and providing general and administrative support for our operations, including the cost associated with operating as a public company. As a result, we will need additional capital to fund our operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements or other sources.

We do not currently have any approved products and have never generated any revenue from product sales. We have financed our operations primarily through proceeds from government grants and from the sale of our convertible preferred stock. As of June 30, 2021, we have raised approximately $81.3 million, including $15.2 million of government grants and $66.1 million from the sale of convertible preferred stock. Our cash, cash equivalents and short-term investments totaled $29.2 million as of March 31, 2021. We had $0.5 million of long-term debt as of March 31, 2021 with a maturity in November 2027.

Cash flows

The following table summarizes our sources and uses of cash for the periods presented (in thousands):

	YEARS ENDED DECEMBER 31,		THREE MONTHS ENDED MARCH 31	
	2019	2020	2020	2021
Net cash (used in) operating activities	$ (5,177)	$ (9,071)	$ (2,214)	$ (5,627)
Net cash provided by (used in) investing activities	(35,741)	38,455	19,282	(229)
Net cash provided by financing activities	21,979	490	1	112
Net increase (decrease) in cash and cash equivalents	$(18,939)	$29,874	$ 17,069	$ (5,744)

Cash flows for the years ended December 31, 2019 and 2020 and the three months ended March 31, 2020 and 2021

Operating activities

Net cash used in operating activities for the year ended December 31, 2019 was $5.2 million, primarily consisting of a net loss of $8.2 million as we incurred expenses associated with our clinical programs. In addition, we had non-cash

charges of $2.6 million for the write off on in process research and development, change in the fair value of the warrant liability, stock-based compensation expense and depreciation and amortization. Net cash used in operating activities was also impacted by $0.5 million in changes in operating assets and liabilities, including an increase of $0.4 million in accrued expenses, $0.3 million in deferred rent, and $13,000 in accounts payable, which were partially offset by an increase of $4,000 in prepaid expenses and a decrease of $125,000 in deferred revenue.

Net cash used in operating activities for the year ended December 31, 2020 was $9.1 million, primarily consisting of a net loss of $17.7 million as we incurred expenses associated with our clinical programs and we increased our headcount. In addition, we had non-cash charges of $6.8 million for the change in the fair value of the warrant liability, stock-based compensation expense and depreciation and amortization. Net cash used in operating activities was also impacted by $1.8 million in changes in operating assets and liabilities, including an increase of $1.5 million in accrued expenses, $0.3 million in accounts payable, $121,000 in deferred rent, and a decrease of $60,000 in prepaid expenses, which were partially offset by an increase of $83,000 in other long term assets and a decrease of $125,000 in deferred revenue.

Net cash used in operating activities for the three months ended March 31, 2020 was $2.2 million, primarily consisting of a net loss of $1.8 million and the impact of non-cash charges for depreciation and amortization and non-cash interest expense of $16,000 and non-cash credits of $455,000 for a decrease in the fair value of the warrant liability and a reduction in non-cash stock compensation expense. Net cash used in operating activities was also impacted by changes in operating assets and liabilities which were insignificant.

Net cash used in operating activities for the three months ended March 31, 2021 was $5.6 million, primarily consisting of a net loss of $4.5 million as we incurred expenses associated with our clinical programs and we increased our headcount, in particular our management team, and the impact of non-cash charges for depreciation and amortization, non-cash stock compensation expense and non-cash interest expense of $477,000. Net cash used in operating activities was also impacted by changes in operating assets and liabilities, including an increase of $173,000 in accounts payable which was offset by a $1.3 million decrease in accrued expenses, a $225,000 increase in prepaids and other current assets and a $277,000 increase in other long term assets.

Investing activities

Net cash used in investing activities for the year ended December 31, 2019 was $35.7 million, which was attributable to a net purchase of $34.7 million in available-for-sale securities, $0.8 million for the purchase of the assets of Periphagen and $0.2 million for purchases of fixed assets.

Net cash provided by investing activities for the year ended December 31, 2020 was $38.4 million, which was attributable to a net sale of $39.9 million in available-for-sale securities and the use of $1.5 million for purchases of fixed assets.

Net cash provided by investing activities for the three months ended March 31, 2020 was $19.3 million, and consisting of the net sale of available-for-sale securities.

Net cash used in investing activities for the three months ended March 31, 2021 was $229,000, and consisted of the purchase of fixed assets.

Financing activities

Net cash provided by financing activities for the year ended December 31, 2019 was $22.0 million, consisting of the $22.5 million of proceeds from the issuance of our Series C convertible preferred stock and $1,000 of proceeds from exercise of stock options and the use of $0.5 million to make payments on notes payable to our founders.

Net cash provided by financing activities for the year ended December 31, 2020 was $490,000 consisting of $460,000 received under the Paycheck Protection Program and $30,000 of proceeds from exercise of stock options.

Net cash provided by financing activities for the three months ended March 31, 2020 was $1,000 and consisting of proceeds from the exercise of stock options.

Net cash provided by financing activities for the three months ended March 31, 2021 was $112,000 and consisting of proceeds from the exercise of stock options and warrants.

Funding requirements

We expect our operating expenses to increase substantially in the future in connection with our ongoing activities, particularly as we advance CAN-2409 and CAN-3110 through research and development, clinical trials, develop our manufacturing capabilities and build and qualify our manufacturing facility, as we research and develop additional

product candidates including preclinical activities and as we prepare for marketing approval and commercialization. In addition, following the closing of this offering, we expect to incur additional costs associated with operating as a public company.

Specifically, our costs and expenses will increase as we:

- advance the clinical development of CAN-2409 and CAN-3110;
- pursue the preclinical and clinical development of other product candidates using our HSV platform;
- develop our manufacturing capabilities, including the construction and qualification of our manufacturing facility; and
- expand our operational, financial, and management systems and increase personnel, including personnel to support our operations as a public company.

We expect to fund continued development and expansion of our manufacturing capabilities, including the construction and qualification of our manufacturing facility, which will include construction costs, equipment, software systems and the cost of engineering production runs, with proceeds from this offering and future financing transactions. These transactions may include the issuance of additional equity or debt or the use of credit line or other bank-sponsored financing resources.

We believe that the anticipated net proceeds from this offering, together with our existing cash, cash equivalents, and short-term investments, will enable us to fund our operating expenses and capital expenditure requirements through the first quarter of 2023. We have based this estimate on assumptions that may prove to be incorrect, and we could utilize our available capital resources sooner than we currently expect.

Because of the numerous risks and uncertainties associated with the research, development, and commercialization of therapeutics, it is difficult to estimate with certainty the amount of our working capital requirements. Our future funding requirements will depend on many factors, including:

- the progress, costs, and results of our clinical development and clinical trials for CAN-2409 and CAN-3110;
- the progress, costs, and results of our additional research and preclinical development programs;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and comparable foreign regulatory authorities, if applicable, for our product candidates;
- the costs and timing of internal process development for our manufacturing capabilities;
- the scope, progress, results, and costs of any product candidates that we may derive from our HSV platform or with collaborators;
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; hire additional personnel in research, manufacturing, and regulatory and clinical development, as well as management personnel;
- the extent to which we in-license or acquire rights to other products, product candidates, or technologies;
- additions or departures of key scientific or management personnel;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales, and distribution for any of our product candidates for which we obtain marketing approval;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval; and
- the costs of operating as a public company.

Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our cash needs through a combination of public or private equity or debt financings and other sources, which may include collaborations strategic alliances and licensing arrangements with third parties. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be diluted, and the terms of these securities may include liquidation or other

preferences that could adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business. If we raise additional funds through other sources, such as collaboration agreements, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, product development, and research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

Contractual obligations and commitments

The following is a summary of our contractual obligations and commitments as of March 31, 2021:

	PAYMENTS DUE BY PERIOD (in thousands)			
	TOTAL	LESS THAN 1 YEAR	1 TO 3 YEARS	3 TO 5 YEARS
Operating lease obligation (1)	$2,489	$ 459	$ 1,378	$ 651
Total	$2,489	$ 459	$ 1,378	$ 651

(1) Represents future minimum lease payments under our operating leases for office and laboratory space at our Needham, Massachusetts facility (see our financial statements included elsewhere in this prospectus for additional information on these lease agreements).

We also enter into contracts in the normal course of business with hospitals, clinics, universities, and other third parties for clinical trials and testing and with construction contractors and process developers for the construction of our manufacturing facility. These contracts do not contain minimum purchase commitments and are cancelable by us upon prior written notice. Payments due upon cancelation consist only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancelation. These payments are not included in the table above as the amount and timing of such payments are not known.

Critical accounting policies and use of estimates

Our management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of our financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience, known trends and events, and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may materially differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to our financial statements included elsewhere in this prospectus, we believe that the following accounting policies are those most significant to the judgments and estimates used in the preparation of our consolidated financial statements.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf, and estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs. Most of our service providers invoice us in arrears for services performed, on a pre-determined schedule

or when contractual milestones are met; however, some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of these estimates with the service providers and make adjustments, if necessary. Examples of estimated accrued research and development expenses include fees paid to the following:

- contractors and vendors working on the construction and development of our commercial-scale manufacturing facility;
- clinical trial sites where patients are being treated with our product candidates; and
- consultants providing services related to process development, regulatory and other services.

Stock-based compensation

We measure stock options and other stock-based awards granted to our employees, directors, consultants, advisors based on the fair value on the date of the grant, awards, net of actual forfeitures, over the requisite service period, which is generally the vesting period of the respective award. For stock-based awards granted to non-employees, compensation expense is recognized over the vesting period which approximates the period over which services are rendered by such non-employees.

We estimate the fair value of each stock option grant on the date of grant using the Black-Scholes option-pricing model, which uses as inputs the fair value of our common stock and assumptions we make for the expected volatility of our common stock, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options, and our expected dividend yield.

Determination of fair value of common stock

As there has been no public market for our common stock to date, the estimated fair value of our common stock has been determined by our board of directors as of the date of each option grant, with input from management, taking into consideration our most recently available third-party valuations of common stock at the time of the grants, as well as our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. Third-party valuations, or valuation reports, were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation.

For the December 31, 2019 valuation report prepared by a third-party, an option pricing allocation method, or OPM, was selected to allocate the total equity value across the various securities outstanding at the time of the valuation. The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. For the December 1, 2020 and January 1, 2021 third-party prepared valuation reports, a probability-weighted expected return method was used to determine the fair value of the common stock. The present value of the common stock under each of these three identified scenarios was weighted based on the probability of each scenario occurring to determine the value of the common stock. These third-party valuations resulted in a valuation of our common stock of $1.55, $3.96, $4.97 and $6.64 per share as of December 31, 2019, December 1, 2020, January 1, 2021 and June 15, 2021, respectively.

In addition to considering the results of the valuation reports, our board of directors considered various objective and subjective factors to determine the fair value of our common stock as of each grant date, including:

- the prices at which we sold shares of convertible preferred stock and the superior rights and preferences of the convertible preferred stock relative to our common stock at the time of each grant;
- the progress of our research and development programs, including the status and results of preclinical studies and clinical trials for our product candidates;
- our stage of development and commercialization and our business strategy;
- external market conditions affecting the biotechnology industry and trends within that industry;
- our financial position, including cash on hand, and our historical and forecasted performance and operating results;
- the lack of an active public market for our common stock and our convertible preferred stock;

- the likelihood of achieving a liquidity event, such as an initial public offering, or IPO, or sale of our company considering prevailing market conditions; and
- the analysis of IPOs and the market performance of similar companies in the biotechnology industry.

The assumptions underlying these valuations were highly complex and subjective and represented management's best estimates, which involved inherent uncertainties and the application of management's judgment. As a result, if we had used different assumptions or estimates, the fair value of our common stock and our stock-based compensation expense could be materially different.

Once a public trading market for our common stock has been established in connection with the completion of this offering, it will no longer be necessary for our board of directors to estimate the fair value of our common stock in connection with our accounting for granted stock options and other such awards we may grant, as the fair value of our common stock will be determined based on the quoted market price of our common stock.

Recent accounting pronouncements

A description of recent accounting pronouncements that may potentially impact our financial position, results of operations, or cash flows is disclosed in Note 2 to our audited consolidated financial statements included elsewhere in this prospectus.

Off-balance sheet arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

Quantitative and qualitative disclosures about market risk

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. Our interest-earning assets consist of cash, cash equivalents and short-term marketable securities, which are denominated in U.S. dollars. We had cash, cash equivalents and short-term marketable securities of $29.2 million, or 83.1% of our total assets, as of March 31, 2021. Interest, dividend, and investment income earned on these assets was $177,000 for the year ended December 31, 2020 and $8,000 for the three months ended March 31, 2021. Our interest income is sensitive to changes in the general level of interest rates, primarily U.S. interest rates. Such interest-earning instruments carry a degree of interest rate risk; however, a change by 10% in interest rates would not have a material impact on our financial position or results of operations during the year ended December 31, 2020 and the three months ended March 31, 2021.

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates.

Inflation generally affects us by increasing our costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the years ended December 31, 2019 and 2020 and the three months ended March 31, 2020 and 2021.

Emerging growth company status

In April 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was enacted. Section 107 of the JOBS Act provides that an "emerging growth company," or an EGC, can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, or the Securities Act, for complying with new or revised accounting standards. Thus, an EGC can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to use the extended transition period for new or revised accounting standards during the period in which we remain an emerging growth company; however, we may adopt certain new or revised accounting standards early.

We will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year in which we have more than $1.07 billion in annual revenue; (2) the date we qualify as a "large accelerated filer," with at least $700.0 million of equity securities held by non-affiliates; (3) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (4) the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

BUSINESS

Overview

We are a late clinical stage biopharmaceutical company focused on helping patients fight cancer with oncolytic viral immunotherapies. Our engineered viruses are designed to induce immunogenic death through direct viral-mediated cytotoxicity in cancer cells, thus releasing tumor neo-antigens and creating a pro-inflammatory microenvironment at the site of injection. Our approach combines an in-depth knowledge of viral immunotherapy with extensive clinical experience across a wide range of indications. Based on the broad range of data that we have generated from our preclinical models and clinical trials using our approach, we have observed what we believe to be systemic immune response against locally injected tumors and their distant metastases. We have established two oncolytic viral immunotherapy platforms based on novel, genetically modified adenovirus and herpes simplex virus (HSV) constructs. In our clinical results to date from CAN-2409, our lead product from our adenovirus platform, and CAN-3110, our lead product candidate from our HSV platform, we have observed that these candidates may have the potential to address significant unmet patient need and improve clinical outcomes in novel indications across broader patient populations.

Our most advanced product candidate, CAN-2409, is an off-the-shelf adenovirus product candidate combined with the prodrug valacyclovir that has generated promising clinical activity across a range of solid tumor indications, including our lead indication of prostate cancer. We are currently conducting, as part of our most advanced CAN-2409 program, a Phase 3 clinical trial in the United States under a Special Protocol Assessment, or SPA, with the FDA for CAN-2409 in patients with newly diagnosed localized prostate cancer who have an intermediate- or high-risk for progression. We expect to complete enrollment for this trial in the third quarter of 2021 with a final data readout in 2024. We are also evaluating CAN-2409 in newly diagnosed high-grade glioma. The FDA has granted CAN-2409 Fast Track designation for use in this setting in combination with standard of care surgery and chemoradiation. We intend to initiate a potential registrational Phase 3 trial in this indication in the first half of 2022.

In addition, we are advancing development of our HSV platform product candidates for solid tumor indications. Our lead HSV product candidate, CAN-3110, is currently in an ongoing investigator-initiated Phase 1 clinical trial in our initial target indication of recurrent high-grade glioma, and we expect to report additional biomarker results in the fourth quarter of 2021. We are also designing novel candidates based on our HSV platform for the treatment of solid tumors.

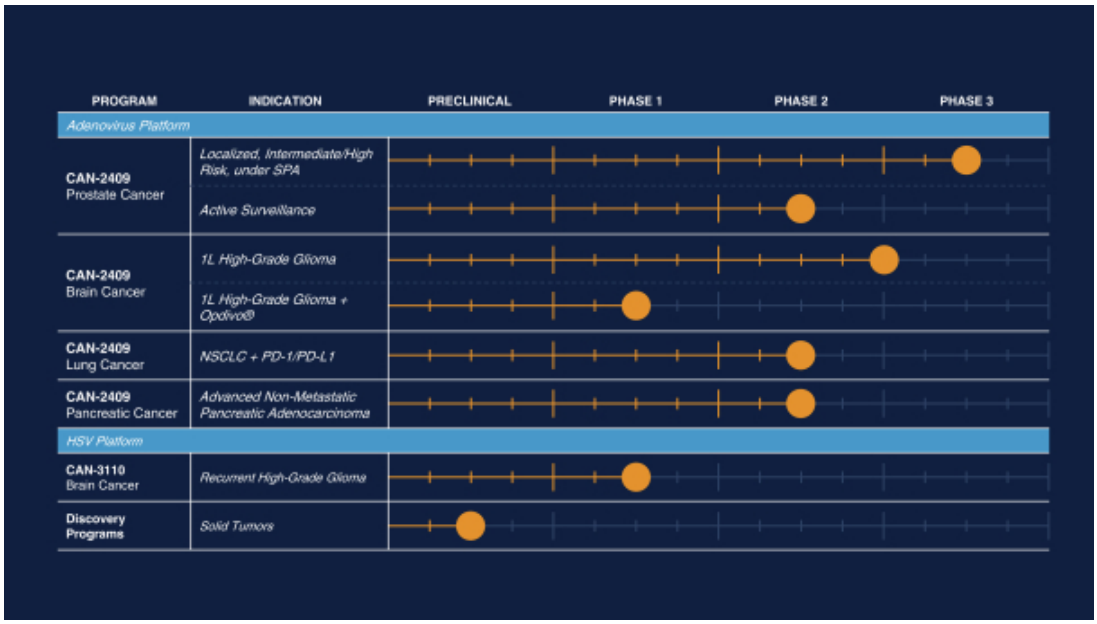
Our oncolytic viral immunotherapy approach utilizes intratumoral administration of genetically engineered viruses to selectively induce tumor cell death and elicit an innate and adaptive anti-tumor immune response. Local delivery enables us to achieve these effects while aiming to minimize systemic toxicity. The immune cells induced by these viral immunotherapies are believed to target patients' specific tumor antigens, potentially improving responses in immunologically "hot" tumors while at the same time infiltrating the tumor microenvironment, transforming non-inflamed "cold" tumors with limited immune response into "hot" tumors. In our data from our clinical studies in patients with cancer, we have observed increases in the expression of immune checkpoints PD-1, PD-L1 and CTLA-4 following treatment with CAN-2409 supporting the evaluation of combinations with immune checkpoint inhibitors (ICI) such as anti-PD-(L)1 that, typically, are only efficacious in patients with immunologically "hot" tumors. While our product candidates are administered directly into the tumor, we have observed systemic immune response in our preclinical studies and clinical trials that may indicate the potential of CAN-2409 and CAN-3110 to induce systemic immune response against distal, uninjected tumors, also known as an "abscopal" effect.

We believe oncolytic viral immunotherapy is among the most promising cancer treatment modalities today. Treatment with oncolytic viral immunotherapy has already been clinically validated through talimogene laherparepvec (Imlygic, Amgen), the first FDA-approved intratumoral oncolytic virus. Our goal is to further improve patient outcomes from oncolytic viral immunotherapies by selecting the optimal vector, specific transgenes and clinical indications for each tumor type while optimizing product candidate attributes, such as high-titer formulation, intratumoral administration, and storage conditions that could potentially lower logistical barriers for patients and clinicians.

Our Pipeline

We have an advanced pipeline comprised of six ongoing clinical trials based on our two lead product candidates. In addition, we own exclusive development and commercial rights for our product candidates in major territories including the United States, Europe and Asia.

Our pipeline is set forth below:



CAN-2409, formerly known as gene mediated cytotoxic immunotherapy, or GMCI, is our most advanced product candidate. It is a replication deficient adenovirus that has been genetically modified to encode the enzyme thymidine kinase. This enzyme activates an orally administered prodrug, valacyclovir, a widely available, generally well-tolerated antiviral at the site of the tumor, generating a powerful patient-specific anti-tumor immune response. We believe there are three key aspects of the mechanism of action. First, the direct, cellular killing activity is based on the transformation of valacyclovir into a toxic nucleotide analogue that disrupts DNA synthesis and repair. This phenomenon occurs preferentially in actively dividing cancer cells, thereby providing tumor specificity. This DNA repair inhibition is also hypothesized to be the mechanistic explanation behind the encouraging pre-clinical and clinical activity of CAN-2409 in combination with radiotherapy, a treatment known to cause DNA breaks requiring repair for continued cellular survival. Second, adenoviral capsid proteins themselves also directly trigger an immunologic response through the establishment of a proinflammatory tumor microenvironment, releasing important cytokines such as GM-CSF and IL-6. We believe this contributes to the potent activation of the patient's own immune system that plays a critical role in the CAN-2409 mechanism of action. Finally, the localized death of tumor cells releases numerous antigens that can be recognized by the patient's own immune system, thereby training the immune system to target and destroy similar cancer cells that have spread to other sites in the body.

CAN-2409 has been administered to over 700 patients with cancer to date, over 500 of whom are in ongoing, placebo-controlled randomized trials. In total, we have conducted more than 10 clinical trials with CAN-2409 in a range of solid tumor indications. We have seen encouraging clinical activity and a favorable tolerability profile with CAN-2409 in both monotherapy and combination settings with radiotherapy, immune checkpoint inhibitor therapy, androgen deprivation therapy (ADT), chemotherapy and surgery. Based on the totality of our clinical data generated to date, we are currently pursuing indications in prostate, brain, lung and pancreatic cancer, which we believe have the greatest potential to address unmet need.

We are conducting a Phase 3 clinical trial with CAN-2409 under agreement with the FDA through the SPA process in newly diagnosed localized prostate cancer in intermediate- and certain high-risk patients in combination with the

standard of care that comprises radiotherapy and optional ADT. Our SPA provides FDA concurrence that our key endpoints and specific critical elements of our trial design are adequate to support a future marketing application if, among other things, we achieve the primary endpoint in the trial. The clinical trial is randomized, triple-blinded and placebo-controlled. It is targeting approximately 700 patients and is expected to be fully enrolled in the third quarter of 2021 with final data readout anticipated in 2024. We have also received Fast Track designation by the FDA for the development of CAN-2409 for the treatment of localized, primary prostate cancer in combination with radiotherapy to improve the local control rate, decrease recurrence and improve disease-free survival. We expect that if the trial is successful and if we obtain FDA approval, CAN-2409 could be the first new FDA approved pharmacologic treatment available in over 30 years as a first line therapeutic for the over 100,000 patients who are newly diagnosed with localized prostate cancer each year in the U.S.

We have also completed enrollment for a Phase 2 clinical trial with CAN-2409 as monotherapy in newly diagnosed prostate cancer patients under active surveillance. This trial has recruited 187 patients with low-, intermediate- and certain high-risk localized prostate cancer. We expect to announce top line data in 2023. We believe that this trial, if successful, could position CAN-2409 as a first line monotherapy treatment of patients with low- and intermediate-risk prostate cancer, thereby meaningfully expanding the addressable patient population.

We have also completed a Phase 1b/2 clinical trial evaluating CAN-2409 in patients with high-grade glioma. Our results demonstrated a statistically significant improvement in overall survival of approximately 3.6 months over standard of care alone (17.1 months versus 13.5 months, p=0.0417) in the overall trial population of high-grade glioma. Additionally, in a pre-specified subgroup of patients diagnosed with glioblastoma who underwent gross total surgical resection, a procedure consisting of the removal of more than 95% of the tumor, an improvement of overall survival of approximately 8.8 months over standard of care alone was demonstrated (25.1 months versus 16.3 months, p=0.0120). We are currently planning a Phase 3 trial in this indication and anticipate commencement in the first half of 2022. CAN-2409 has also received Fast Track designation for use in combination with standard of care surgery and chemoradiation to improve overall survival in adults with newly diagnosed glioblastoma. We have also received Orphan Drug designation for the use of CAN-2409 for treatment of malignant brain tumors, including high-grade glioma. In addition, we have established a clinical collaboration with both Bristol-Myers Squibb Company (BMS) and the Adult Brain Tumor Consortium (ABTC), a National Cancer Institute funded cooperative group of leading brain cancer centers that facilitates the execution of novel, early-stage trials at some of the leading brain cancer treatment centers. This collaboration has provided support for our ongoing Phase 1 clinical trial in high-grade glioma patients, testing the combination of CAN-2409 and nivolumab (Opdivo, BMS). We anticipate reporting safety and initial efficacy data from this trial in the first half of 2022.

In NSCLC, we have initiated a Phase 2 clinical trial evaluating CAN-2409 in combination with PD-(L)1 checkpoint inhibitors. This open label trial is targeting enrollment of approximately 111 patients with stage III/IV NSCLC. The primary efficacy endpoint for this trial is response rate measured by response evaluation criteria in solid tumors (RECIST) and we expect to report safety and initial clinical activity in the first half of 2022.

Our second oncolytic viral immunotherapy platform is based on a novel, next generation, genetically modified HSV that induces tumor specific oncolysis. The HSV platform enables generation of both replication-competent and replication-deficient viral product candidates as well as capacity to clone, in the vector, up to five transgenes that will allow us to optimize our virus profile for different tumor settings. CAN-3110, our first HSV product candidate, has been engineered for enhanced specificity and tumor cell killing, while minimizing toxicity on healthy tissue. CAN-3110 was formerly known as rQNestin34.5v.2. An investigator-initiated Phase 1 clinical trial is ongoing with CAN-3110 in our initial target indication of recurrent high-grade glioma and we anticipate reporting additional biomarker results in the fourth quarter of 2021. Based on the molecular targeting of CAN-3110, we believe that it could be evaluated in an expanded range of indications in the future, such as other neurologic tumors, gastrointestinal stromal tumors, thyroid tumors and breast cancer. In addition, we are pursuing novel solid tumor discovery programs based on our HSV platform.

Corporate History and Our Team and Investors

Following the combination of our predecessor company, Advantagene, Inc. (Advantagene), with the HSV discovery platform assets acquired from Periphagen, a company focused on engineering HSV as a gene therapy vector, we formally changed our name to Candel Therapeutics, Inc. in December 2020. Advantagene was built on a strong

scientific foundation and developed CAN-2409 over years of research and development. In December 2019, Advantagene acquired substantially all the assets of Periphagen and in September 2020, licensed CAN-3110 from Mass General Brigham (formerly known as The Brigham and Women's Hospital).

We were founded and are now led by a team of renowned drug developers, oncolytic viral immunotherapy experts, oncologists, immunologists and biotech business leaders.

- *Paul Peter Tak, M.D., Ph.D.*, *FMedSci*. Dr. Tak, our President and CEO, joined us in September 2020 and most recently served as President and CEO of Kintai Therapeutics. Prior to his position at Kintai, he served as Senior Vice President, Chief Immunology Officer, and Global Development Leader at GlaxoSmithKline, where he created a pipeline of medicines in immunology and oncology. He has also trained as an internist and immunologist and served as a professor of medicine at the AMC/University of Amsterdam. Dr. Tak also founded the gene therapy company Arthrogen and the immunometabolism company Sitryx.
- *Estuardo Aguilar-Cordova, M.D., Ph.D.* Dr. Aguilar-Cordova is our founder and Chief Scientific Officer. Prior to starting Candel, he was deputy director of the Harvard Gene Therapy Initiative at Harvard Medical School and was on faculty at Baylor College of Medicine where he first became involved in viral immunotherapy in the 1990's.
- *Laura Aguilar, M.D., Ph.D*. Dr. Aguilar has served as our Chief Medical Officer since 2014. Before joining Candel, she was an attending physician in pediatric oncology at the Dana Farber Cancer Institute.
- *Nathan Caffo*. Mr. Caffo is our Chief Business Officer. He was most recently the Chief Business Officer of ALX Oncology where he played a key role in the company's initial public offering. Prior to ALX Oncology, he was the President and CEO of Presage Biosciences, a company focused on intratumoral delivery of oncology agents. To date, Mr. Caffo has raised over $300 million in equity financing over his career.
- *John Canepa*. Mr. Canepa is our Chief Financial Officer. He was most recently Senior Advisor, Acting CFO at Frequency Therapeutics, where he completed several public and private financings including the company's initial public offering. Prior to his position at Frequency Therapeutics, Mr. Canepa served as CFO of Agilis Pharmaceuticals and was instrumental in its sale to PTC Therapeutics. Prior to that, he was COO and CFO of Asterand Bioscience and led its sale to a private equity group. Mr. Canepa was an audit partner at Arthur Andersen for 23 years where he led the firm's worldwide life sciences practice.

We are backed by a group of leading institutional life science investors, including PBM Capital, Northpond Ventures and Sands Capital Ventures.

We believe in the power of collective intelligence when tackling important challenges. We have therefore sought to involve external perspectives through the formation of our Research Advisory Board that includes eminent immunologists, drug development and oncology experts. Members of the Research Advisory Board are selected based on their ability to contribute meaningful viewpoints to Candel's internal scientific, clinical and strategic discussions in which they directly participate. There is no fixed term of service for Research Advisory Board members. Some Research Advisory Board members are compensated as described below.

The current members of our Research Advisory Board are as follows:

- James Allison, Ph.D., *Chair of the Department of Immunology, MD Anderson Cancer Center, Director of the Parker Institute for Cancer Research, Awardee of 2018 Nobel Prize in Physiology or Medicine*
- Edward J. Benz, Jr., M.D., *President and CEO Emeritus, Dana-Farber Cancer Institute*
- Henry Brem, M.D., *Director, Department of Neurosurgery, Professor of Neurosurgery, Johns Hopkins University*
- Roy Herbst, M.D., Ph.D., *Chief of Medical Oncology, Yale Cancer Center*
- Elizabeth Jaffee, M.D., *Deputy Director, Sidney Kimmel Cancer Center at Johns Hopkins University*
- Philip Kantoff, M.D., *Chair, Department of Medicine, Memorial Sloan Kettering Cancer Center*
- Padmanee Sharma, M.D., Ph.D., *Professor of Genitourinary Medical Oncology and Immunology, MD Anderson Cancer Center*

Dr. Benz is a member of our board of directors and is compensated solely in that capacity. See “Management—Director Compensation.” We pay members of our Research Advisory Board that are not also members of our board of directors cash compensation in amounts equal to no more than $120,000 per year per advisor, and also grant certain of such Research Advisory Board members options to purchase or common stock, subject to compliance with applicable conflict of interest rules.

Our Strengths

We believe our experience and capabilities in oncolytic viral immunotherapy will bring significant benefit to cancer patients who are underserved by the current standard of care, particularly in prostate and brain cancer. We believe our key strengths are:

- **Deep clinical and development experience in innovative oncolytic viral immunotherapy.** We are leveraging more than 20 years of development history, and have deployed our lead product candidate CAN-2409 in a range of oncology indications. These efforts have generated extensive clinical data in hundreds of patients and has driven our current development focus. We continue to leverage this depth of clinical data to select new indications of interest and to efficiently execute on our clinical development strategy. We are currently developing our two product candidates in seven clinical trials.
- **Two potentially registrational trials for our CAN-2409 programs in localized prostate and high-grade glioma, indications with significant unmet need supported by encouraging Phase 2 data.**
  - ***Localized prostate cancer:*** Current therapeutic options for early treatment of localized prostate cancer are limited and generally characterized by poor tolerability. A significant proportion of patients experience disease progression after receiving standard of care treatment. Based on our Phase 2 study, intermediate-risk patients receiving CAN-2409 demonstrated failure rates which were 75% lower than the outcomes reported in four large, contemporaneous clinical trials in patients with comparable disease status who were treated with similar radiotherapy protocols, although this is limited because we have not conducted head-to-head studies. Based on the strength of this Phase 2 data, we are currently conducting a Phase 3 trial under an SPA agreement with the FDA.
  - ***High-grade glioma:*** There is presently a large unmet need in this first line patient population with current treatment options, such as temozolomide, demonstrating an overall survival benefit of only 2.5 months over radiotherapy alone. In our Phase 1b/2 clinical trial of patients with newly diagnosed high-grade gliomas, we compared the administration of CAN-2409 combined with standard of care to the effects of standard of care alone. In this overall population, we demonstrated a statistically significant increase in median overall survival (mOS) of 17.1 months compared to 13.5 months observed in the standard of care arm. We believe that the beneficial effect of CAN-2409 can be further improved in the context of a precision medicine approach based on the pre-specified subgroup of patients with glioblastoma whose surgery achieved a gross total resection. In this population, CAN-2409 with standard of care demonstrated a mOS of 25.1 months compared to 16.3 months in the standard of care arm. We are pursuing this precision strategy in our Phase 3 clinical trial.
- **Two oncolytic viral immunotherapy platforms provide versatility and optionality to pursue a range of solid tumor indications.** With our clinical stage engineered adenovirus and HSV platforms, we can approach indications of interest through multiple modalities, expanding our potential to address patients in areas with high unmet need. For example, we are currently conducting clinical trials in two different brain cancer indications with CAN-2409 and CAN-3110.
- **Attractive commercial profile and ownership of our programs.** We currently own development and commercialization rights for our programs in major markets, including the U.S., Europe and Asia, allowing us to control development and seek approval in those areas as we prepare our commercialization efforts.
- **Fully-integrated manufacturing strategy**. We expect that our cost-of-goods will be substantially lower than cell- and antibody-based therapies because of our high-yield manufacturing process. We plan to manufacture our therapeutics for commercialization at our own facility and at third-party manufacturers.

Our Strategy

Our goal is to develop best-in-class oncolytic viral immunotherapies to transform the lives of cancer patients. We plan to develop and commercialize our two lead product candidates, CAN-2409 and CAN-3110, for the treatment of

a broad range of solid tumor indications, while continuing to build our pipeline through our discovery platform. Key elements of our strategy include the following:

- *Advance the late stage development of, and seek regulatory approval for, our lead product candidate, CAN-2409, in newly diagnosed, localized prostate cancer.* We are currently conducting a potentially registrational Phase 3 clinical trial in intermediate- and high-risk patients in combination with the standard of care, radiotherapy. If approved, we believe CAN-2409 could be a first-in-class drug for localized prostate cancer patients with the potential to reduce disease progression and recurrence.
- *Advance the development of, and seek regulatory approval for, CAN-2409 in both monotherapy and combination therapy for high-grade glioma.* We have completed a Phase 2 clinical trial that showed a statistically significant overall survival benefit of approximately 8.8 months in first line glioblastoma patients who underwent gross total resection. We plan to initiate a Phase 3 trial employing a precision medicine approach in this indication in the first half of 2022. We have also entered into a collaboration with BMS and ABTC for a Phase 1b clinical trial in high-grade glioma patients testing the combination of CAN-2409 and nivolumab (Opdivo, BMS), with safety and initial efficacy data expected in the first quarter of 2022.
- *Advance the clinical development of CAN-3110, an oncolytic HSV with tumor-specific enhanced replication potency.* An investigator-initiated Phase 1 clinical trial is ongoing in recurrent glioblastoma with additional biomarker data expected in the fourth quarter of 2021. This trial will evaluate the activity of CAN-3110 in later stage disease, where we believe a replicating virus may present therapeutic advantages.
- *Continue to expand the development of CAN-2409 in other solid tumor indications, including NSCLC and pancreatic cancer.* We believe we can leverage our broad clinical experience to expand the development of CAN-2409 in other indications. We have initiated a Phase 2 clinical trial in patients with NSCLC in combination with PD-(L)1. We have also initiated a Phase 2 clinical trial in patients with advanced non-metastatic pancreatic adenocarcinoma. Our experience in these indications may enable us to expand in the future into other indications.
- *Leverage our HSV oncolytic viral immunotherapy platform to develop additional HSV product candidates.* Our platform enables rapid vector engineering and generation of new candidates. Key attributes of HSV that allow targeted modifications to the virus are high capacity for genetic cargo, and the ability of our platform to generate both replication incompetent and competent agents depending on the demands of a particular application.
- *Develop strategic partnerships to maximize the value of our current and future product candidates.* In order to advance treatment options for a large number of patients, we may partner with other companies with complementary resources to maximize the value of our current and future product candidates. Such partnerships may allow us to pair CAN-2409, CAN-3110 and our future product candidates with other novel agents owned by strategic partners. Partnerships may also help realize the full potential of our product candidates in markets where we are unlikely to pursue development or commercialization on our own. We intend to maintain significant economic interest in our product candidates and selectively consider partnership opportunities.
- *Complete our planned cGMP manufacturing facility*. We expect to develop commercial scale, fully integrated manufacturing capabilities at our facility in Needham, Massachusetts. We will also rely on third-party contract manufacturers for clinical trial product supplies and for commercial scale manufacturing. By investing in our own manufacturing facilities, we are positioning ourselves to leverage the off-the-shelf profile of our product candidates, by ensuring consistent and adequate commercial supply, while enabling efficient production with a low cost of goods.

Our Market Opportunities in Localized Prostate Cancer and High-Grade Glioma

The two indications where we have the most advanced clinical trials are localized prostate cancer and high-grade glioma. These types of cancer present substantial market opportunities.

Prostate cancer is the second leading cause of cancer death among men in the U.S. The prostate cancer therapy market is estimated to be approximately $9.9 billion in 2019 growing to over $16.1 billion by 2026. Although most deaths occur in patients with later stage metastatic disease, the majority of prostate cancer patients, roughly 150,000 annually in the U.S., are initially diagnosed in the early stage of disease. Standard of care in this early,

localized setting, leaves substantial need unaddressed. The primary interventions are surgery, radiotherapy and androgen deprivation therapy, also known as chemical castration. These treatments have high incidence of potentially life altering side effects, including incontinence and erectile dysfunction. There is therefore a significant unmet need for a novel treatment able to forestall or prevent progression to later stages of disease without the burdensome side effects associated with the current standard of care.

Glioblastoma is the most common form of brain cancer, comprising approximately 90% of high-grade gliomas, and has an extremely poor prognosis. Fewer than 10% of patients survive longer than 5 years, with a median overall survival of less than 15 months. The primary standard of care treatments are surgery, radiotherapy and chemotherapy. None of these treatments offer the potential of a cure, with nearly all patients eventually succumbing to their cancer. While the annual number of drug-treatable patients with glioblastoma in the U.S. is approximately 16,000, limited treatment options and the substantial unmet need present a significant market opportunity. One illustrative example is the agent temozolomide, which demonstrated improvement in median overall survival of less than three months compared to standard of care, yet still generated peak annual revenue of over $1 billion.

Our Approach

Conventional cancer therapies (chemotherapy, radiotherapy and surgery) often do not eradicate 100% of the tumor cells, which often leads to tumor progression or recurrence. Deep and durable responses, therefore, are still elusive for many cancer patients. Traditionally, surgery and/or radiotherapy are used for local tumor debulking whereas chemotherapeutic agents target systemic eradication of tumor cells. These treatment modalities, however, are often limited by toxicity.

Immunotherapy is a relatively new treatment modality that has expanded the anti-cancer treatment paradigm. FDA-approved immunotherapies include cytokines, cell therapies and antibodies, including checkpoint inhibitors. Much focus has been placed on harnessing the effector T cell arm of the immune system for tumor specific immunity. Adoptive T cell therapy has shown positive results but with limited activity in solid tumors, and is not scalable for widespread use. Vaccine approaches range in complexity from peptide antigens to autologous or allogeneic tumor cell products. The advantage of the single antigen approaches is that they can be easily manufactured and produced, however, they have the fundamental disadvantage of being potentially irrelevant for a patient's specific tumor or immune system or easily bypassed by resistant clones. Cellular vaccines are not easily scalable and allogeneic vaccines may not bear the relevant antigens expressed by a patient's tumor. Immune checkpoint inhibitors, or ICI, such as anti-PD-1 and anti-PD-L1 antibodies, have transformed the treatment paradigm for different cancer indications. However, only approximately 15 to 40% of patients overall respond to such treatment.

We are focused on the development of oncolytic viral immunotherapy approaches, which are based on an extensive history of research. Originally, the mechanism of action of those agents was believed to be based only on the ability of the virus to induce cancer cell lysis and to resolve tumors. Later, it was demonstrated that viral immunotherapy may induce immunogenic cell death. This effect may be enhanced by the pro-inflammatory effects of the viral capsid proteins. With the dramatic emergence of ICIs and immunotherapy as a core treatment modality, the importance of the immunostimulatory aspect of viral-mediated approaches became more widely evident. The currently understood generalized mechanism of action of oncolytic viral immunotherapies is unique in combining both an anti-tumor cytotoxic component and an immune-stimulatory component. Together, these modalities lead to an "*in-situ* vaccination" effect against the tumor.

Pairing this therapeutic approach with ICI treatment is based on a strong mechanistic rationale and has shown promise in experimental models of cancer. It has been observed that tumors that are least responsive to ICI are commonly characterized by low levels of lymphocytic infiltration and low or no PD-L1 expression levels; they are referred to as "cold" tumors. One of our areas of focus is the conversion of immunologically suppressed "cold" tumors into immunologically active "hot" tumors, thereby increasing their responsiveness to ICI.

Specific aspects of the mechanism of action of viral immunotherapy include the following:

Direct anti-tumor cytotoxic activity. Tumor specific viral mediated oncolysis is achieved by both precise delivery of the engineered virus to the tumor as well as the virus' ability to selectively replicate within a cancer cell. Various approaches have been applied in different programs to increase the specificity and potency of viral toxicity aimed at tumor cells, including genetic modifications and use of prodrugs.

Broad stimulation of anti-tumor immunity. The immunogenic cell death driven by oncolysis results in a potent local and systemic immune stimulation with the increased expression of proinflammatory cytokines, chemokines and adhesion molecules. This, in turn, promotes the activation of both the innate and adaptive arms of the immune system in the presence of highly immunogenic viral components. This broad response commonly includes recruitment and activation of antigen-presenting cells and effector immune cells to the site of the tumor.

Priming of the immune system against tumor antigens. The lysis of cancer cells leads to the exposure of tumor-specific antigens. This early effect, combined with intratumoral immune cell infiltration and activation, leads to antigen presentation and initiation of a local adaptive immune response targeted against a set of tumor antigens expressed by the patient's cancer cells.

Development of a systemic immune memory response. Viral immunotherapy induces the development of a long-lasting systemic immune surveillance against the antigens associated with the injected tumor, and consequently, tumor antigens expressed at metastatic sites. This, leads to a cytotoxic immune response against the distant tumor cells, also known as an abscopal effect.

Desirable clinical properties. Viral immunotherapy has attributes that are important for a cancer therapeutic. The agents are off-the-shelf, and while they have been shown to stimulate immune responses in certain patients, there is no requirement to modify them for each patient, unlike other cellular therapy approaches. The first viral immunotherapy (Imlygic, Amgen) was approved by the FDA in 2015, providing support that additional agents in this class may have similar potential. Furthermore, safety data shown in the clinical trials and the ultimate approval of Imlygic, supports the ability to combine viral immunotherapy with other agents due to the potential for fewer overlapping side effects.

Our Product Candidates: Two platforms and two clinical candidates to address diverse clinical needs

Our two platforms, one based on adenovirus and the other based on HSV, provide different and complementary sets of attributes, which allows us to utilize the product candidate that is best suited for a particular clinical application.

Key attributes across our oncolytic viral immunotherapy platforms include:

- *Targeting a Wide Range of Cell Types.* Product candidates from both the HSV and adenoviral platforms can transduce a diverse range of cell types, which we believe will allow us to address many different forms of cancer.
- *Off-the-Shelf Product.* A standardized product supports straightforward clinical administration, simplified manufacturing and supply chain management.
- *Intratumoral Route of Administration.* Both of our product candidates are administered by direct injection into the tumor site. This aims to maximize immune stimulation and minimize systemic toxicity, factors that are believed to be suboptimal with intravenous administration. For the indications that we selected, this is a straightforward procedure, leveraging standard of care medical procedures, such as intra-prostate injection or delivery during diagnostic (bronchoscopy) or therapeutic (neurosurgery) procedures.
- *Cost-efficient Manufacturing.* Both product candidates are relatively inexpensive to manufacture, particularly when compared to other biologic or cellular therapy treatments.

Key attributes of our Adenoviral platform include:

- *Targeting a Wide Range of Cell Types.* Adenoviruses can efficiently transduce cells from different lineages. This allows us to apply this platform to many different tumor types.
- *Immunogenic Virus Particle.* The adenoviral virus particles are strong simulators of the innate immune system, a property that contributes to immune activation at the site of administration.
- *High-Titer Formulation.* Adenovirus can be formulated at high titers, facilitating the administration of low volume doses sufficiently potent to induce strong activity, particularly in volume sensitive indications such as brain cancer.
- *Product Stability.* The formulation deployed in clinical trials has stability at refrigerator temperatures (4°C), supporting use at less specialized and therefore widely accessible sites such as community-based private clinics.

- *Non-Replicating Design*. Engineering the adenovirus to remove replication ability reduces the potential for viral shedding, something which is particularly important in clinical applications such as prostate cancer. There is no need for *in vivo* amplification as the virus is highly immunogenic and can be administered at high titers.

Key Attributes of our HSV platform include:

- *Amenable to Engineered Modifications.* Our knowledge of virus biology allows us to make modifications, such as those already present in CAN-3110 to target certain tumor types. The tumor specific replication ability of CAN-3110 is regulated by the expression of ICP34.5, a gene encoding for a protein that permits viral replication even in the presence of the interferon response that is normally able to quell viral infection. In the CAN-3110 construct, ICP34.5 expression is driven in gliomas, but not in healthy brain tissue, thereby enabling replication specifically in the context of brain tumors. We believe our HSV platform will allow us to implement additional genetic modifications to leverage the use of CAN-3110 in high-grade glioma and in other tumor types.
- *Capacity for Replication.* There is a strong rationale for use of a replication-competent virus that is designed to provide potent oncolysis and *in vivo* virus amplification in high tumor volume or less anatomically accessible tumors, such as recurrent high-grade glioma.
- *Lower Immunostimulatory Potency.* The engineered HSV viral particle is able to persist and replicate at the site of the tumor. This is particularly important in larger tumors formed in immune privileged, highly immunosuppressive sites; supporting the use of CAN-3110 in recurrent high-grade glioma.
- *High Capacity for Genetic Cargos*. Our HSV platform allows the introduction of large genetic cargos, such as multiple immunomodulatory genes that may further enhance the anti-tumor immune response.

Our Lead Product Candidate: CAN-2409

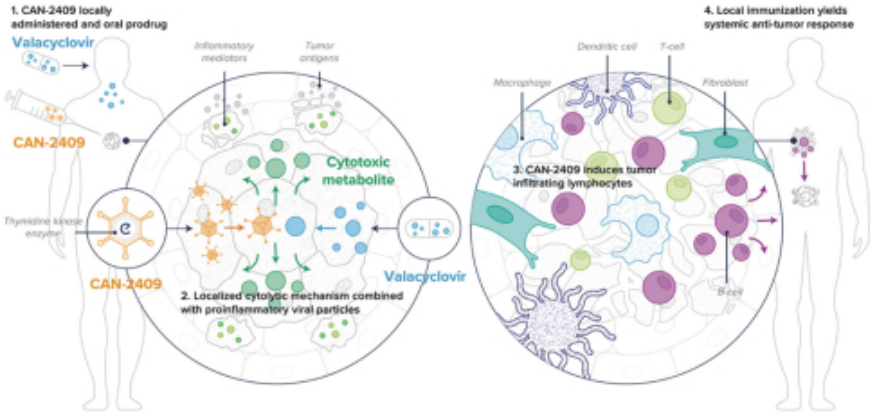
We believe the adenovirus-based CAN-2409 has advantageous properties that differentiate from other viral immunotherapies. Namely, CAN-2409:

- *Has shown activity in a range of solid tumor types and in late-stage clinical trials.*
- *Has been dosed in hundreds of patients and has shown a favorable tolerability profile.*
- *Is engineered to be potently immunogenic but non-replicating with the goal of maximizing the immune response while minimizing the risk for local and systemic toxicity.*
- *Can be stored at 4°C, facilitating the use of CAN-2409 in out-patient clinics. This aspect is particularly favorable in indications such as prostate cancer, where patients are often monitored in individual private practices.*

CAN-2409 (international non-proprietary name: aglatimagene besadenovec) is an adenovirus-based replication-deficient engineered gene construct encoding the thymidine kinase gene derived from the herpes simplex virus. It is injected directly into the tumor or target tissue. Localized injection is intended to minimize systemic toxicities associated with systemic intravenous administration, eliminating the requirement for complex immune evasion or tumor-specific targeting mechanisms, and focuses the immune response locally against the tumor, while also activating the desired systemic anti-tumoral response. The adenoviral construct is used as a vector to transport the thymidine kinase gene into the tumor cells at the site of injection. Thymidine kinase converts generic, FDA-approved anti-herpes drugs, such as ganciclovir, acyclovir and valacyclovir, which we use as prodrugs, into a toxic nucleotide analogue. These agents are widely available, inexpensive and are generally well-tolerated. Cells transduced with thymidine kinase gene undergo immunogenic cell death after exposure to these systemically administered prodrugs.

The prodrug-derived cytotoxic nucleotide analogs are designed to inhibit DNA replication and repair, leading to the death of multiplying tumor cells, and in particular of cells undergoing repair from radiation or chemotherapy damage. This oncolytic activity is immunogenic and exposes tumor antigens that can elicit a further tumor-specific immune response. Additionally, the virus itself stimulates a marked immune response.

CAN-2409: Mechanism of action - local immune activation

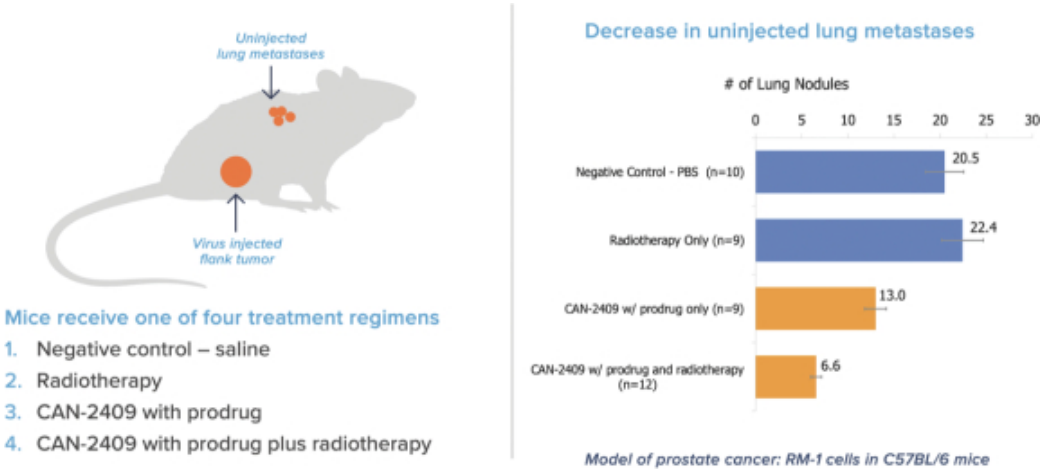


Key pro-inflammatory cytokines such as GM-CSF and IL-6 as well as chemokines, adhesion molecules and costimulatory molecules are locally upregulated, resulting in an inflamed (hot) tumor microenvironment, able to further enhance T cell activation.

This local effect provides a strong mechanistic rationale for the combination of oncolytic viral immunotherapy with T cell checkpoint inhibitors such as PD-1 or PD-L1 targeting antibodies. ICI agents work by unmasking the inhibitory signals provided by PD-L1 ligands on tumor cells when bound to PD-1 receptors on T cells. By blocking this suppressive signal pharmacologically, it has been demonstrated that T cells can be unleashed to attack cancer cells and that profound clinical benefit can be achieved, but this benefit accrues only to a minority of patients. It has been hypothesized that treatment results can be significantly improved by optimizing recognition of the specific tumor antigens by the patient's adaptive immune system using oncolytic viral immunotherapy combined with the non-specific stimulation of T cells induced by ICI treatment. It appears that a duality of signals is required: releasing the checkpoint inhibition as described earlier, coupled with the provision of a positive, stimulatory signal to T cells. The efficient presentation of tumor specific antigens by MHC class I molecules to the immune system provides just such a specific, stimulatory signal. Oncolytic viral immunotherapies have been shown to facilitate such cross presentation of tumor antigens and are therefore an attractive complement to PD-1 or PD-L1 checkpoint blockade.

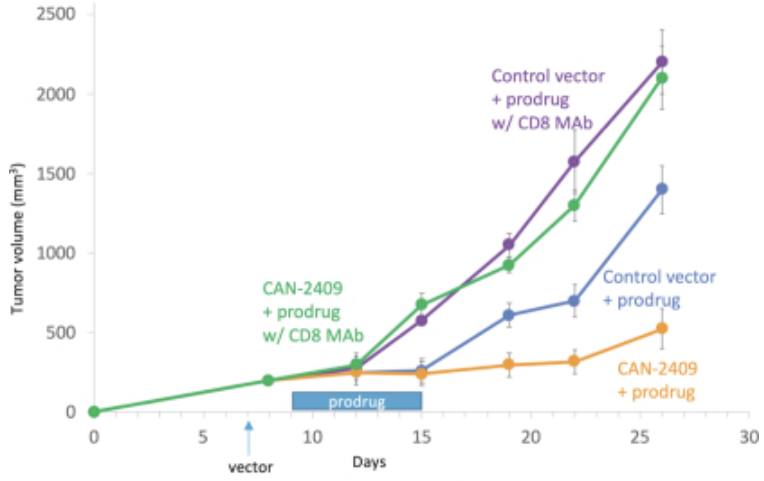
The immune system is highly dynamic, with continuous trafficking of different populations of immune cells throughout the body. One outcome of this is that when T cells are locally activated against tumor-specific antigens, they can act systemically to drive an efficient immune response at sites distant from the original tumor, as is illustrated schematically in the figure above. This abscopal effect may explain the significant effects observed at distant, uninjected sites demonstrated in experimental model of cancers. Abscopal effect has been shown with CAN-2409 in a mouse model of prostate cancer. The model employed RM-1, a syngeneic prostate cell line, that was implanted both in the flanks of the mice as well as systemic, via a tail vein injection to mimic metastatic disease, resulting in the emergence of lung tumor nodules. After intratumor treatment of the flank tumor masses with either CAN-2409 and systemic prodrug, alone or in combination with radiotherapy, we observed a beneficial response in both injected and uninjected metastatic tumor. Use of CAN-2409 resulted in a 38% mean reduction in tumor volume and, in the combination arm, a reduction of 61% in tumor volume. Notably, the number of lung nodules was reduced from 20.5 in the control arm and 22.4 in the mice that received radiotherapy to 13.0 in the CAN-2409 arm, to 6.6 when CAN-2409 was combined with radiotherapy.

CAN-2409 treatment teaches the immune system how to fight cancer in injected tumor and uninjected metastases



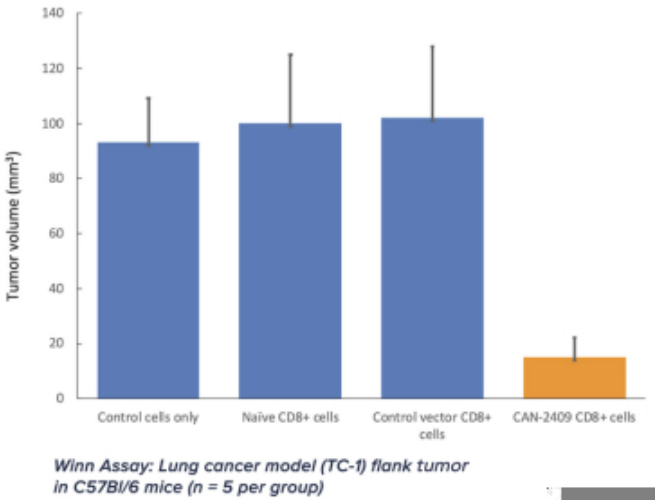
The activity of CAN-2409 treatment has been shown to be dependent on CD8+ T cell involvement in mouse studies that evaluated permutations of CAN-2409 treatment and T cell depletion. In the figure below, experimental data show that in mice bearing AKR flank xenografts that were treated with CAN-2409 and prodrug, significant tumor growth inhibition was observed. In contrast, mice treated with the prodrug and a negative control vector showed significantly less tumor growth inhibition, providing evidence that the specific adenoviral construct of CAN-2409 is a key factor in anti-tumor activity. Moreover, when two additional arms were treated as just described but with the addition of an antibody that depleted CD8+ T cells, very little tumor growth inhibition was observed. This supports the contention that the activity of CAN-2409 treatment is directly dependent on CD8+ T cells. Furthermore, T cells from mice that were successfully treated with CAN-2409 and prodrug were shown to be sufficient to inhibit tumor growth when mixed with AKR tumor model cells and implanted subcutaneously in mouse flanks. This activity was not observed with T cells from untreated mice, from mice that were treated with a control vector that lacked the thymidine kinase gene, or when the AKR tumor cells were xenografted alone. These data are consistent with a T cell dependent mechanism of action of CAN-2409.

CAN-2409 Mechanism of action – T cell dependent anti-tumor activity



Esophageal cancer model (AKR) flank tumor in C57Bl/6 mice (n = 8 per group)

CAN-2409 Mechanism of action – Response to CAN-2409 treatment is transferable via CD8+ T cells in mouse models of cancer



Winn Assay: Lung cancer model (TC-1) flank tumor in C57Bl/6 mice (n = 5 per group)

CAN-3110 and the HSV platform technology

CAN-3110 is a modified HSV with specific properties that can be leveraged in diverse clinical indications. Namely, CAN-3110:

- *Is engineered to provide oncolysis through tumor replication specifically in Nestin expressing cancer cells.*
- *Has demonstrated statistically significant survival benefit in preclinical models of brain cancer.*
- *Has demonstrated a favorable tolerability profile, not reaching a dose limiting toxicity in the dose range tested in our Phase 1 trial.*
- *Has shown a preliminary clinical signal in a difficult to treat brain cancer population, critically defined by a highly immunosuppressive environment.*

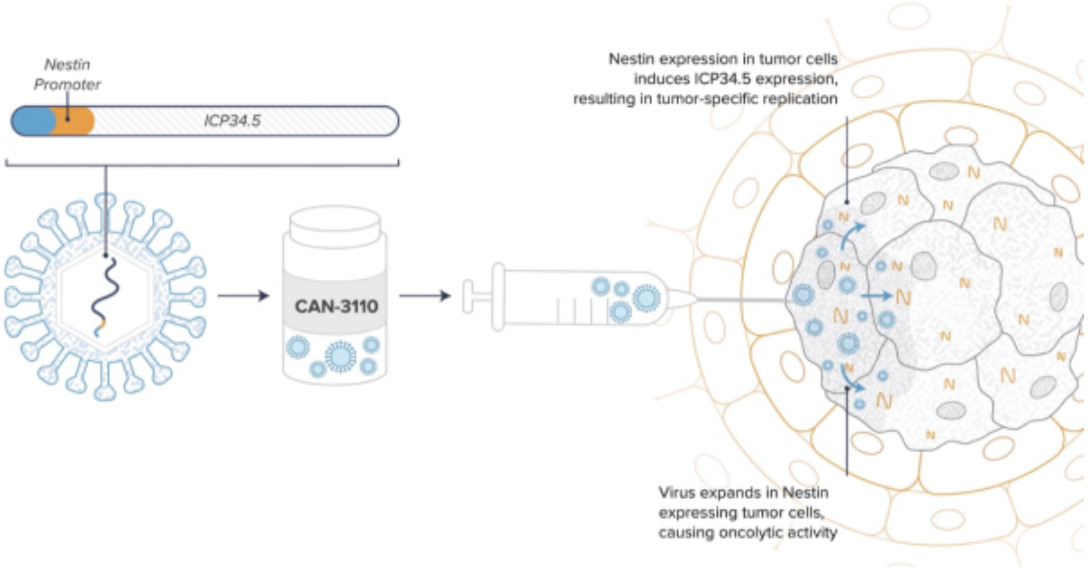
- *Has been engineered to replicate in a range of other indications characterized by Nestin expression.*
- *Is derived from the HSV platform that also provides the potential to support expansion of our pipeline with novel agents.*

CAN-3110 is an engineered oncolytic HSV where the expression of ICP34.5, the gene responsible for viral replication, has been placed under the control of a tumor-specific Nestin promoter. This modification of the viral genome enables us to maintain the function of ICP34.5, an HSV protein that allows virus replication even in the presence of a suppressive interferon response, under a strict control and only in tumor cells.

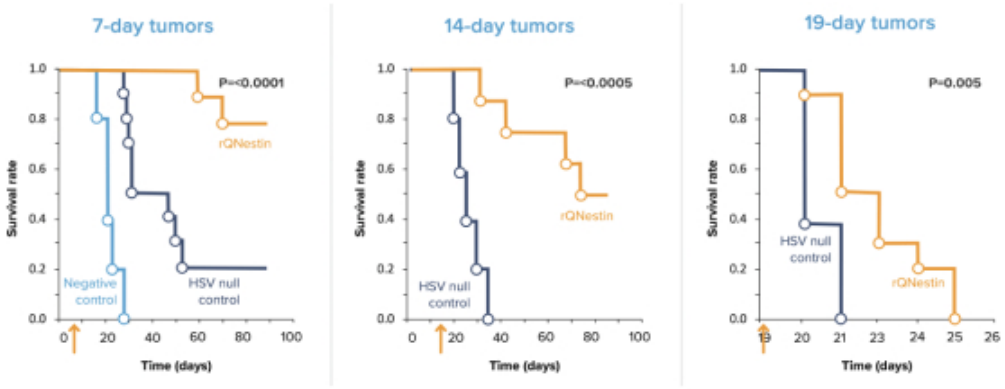
ICP34.5 is often deleted in other HSV oncolytic viruses that may be less tumor selective with an intent of achieving favorable safety profile, but this often results in weak viruses characterized by poor replication ability and an ability to generate limited immune response.

Nestin is a cytoskeletal protein that is overexpressed in glioma cells, but it is absent in the healthy adult brain. In CAN-3110, ICP34.5 expression is controlled by the Nestin promotor enabling viral replication selectively in tumor cells. This replication-competent HSV construct provides tumor-specific cytolytic activity in animal models, while sparing healthy cells. As set forth below, data with a tool analogue of CAN-3110 in a mouse model of glioma has shown survival benefit over control vectors when the agent is administered to mice at both early and late stages of tumor growth, even after tumor implantation has led to neuropathology.

CAN-3110: HSV “Nestin 34.5” construct



Survival Benefit after rQNestin (CAN-3110 tool compound) treatment in mouse model of high-grade glioma



Model: human U87dEGFR glioma cells in athymic mice

Our technology platform enables rapid HSV vector engineering and generation of new therapeutic candidates. Our platform allows rapid and precise modifications to the virus including the insertion of high cargo capacity DNA cargo cassettes, generation of both replication incompetent and competent agents, and other attributes which provide the opportunity to optimally design HSV technologies for specific therapeutic applications in oncolytic and immunotherapeutic indications. Our team has produced and released HSV vectors for multiple human clinical trials. Our HSV discovery platform allows us to feed and fill our pipeline, building on our vast experience in developing oncolytic viral immunotherapies.

Intratumoral administration

Both CAN-2409 and CAN-3110 are intentionally administered intratumorally. We believe that directly injecting these oncolytic viral immunotherapies into a patient's cancerous tissue helps to optimize the benefit/risk for these agents to be highly immunostimulatory at the site of the tumor, whereas systemically administered agents would need to avoid detection by the body's immune surveillance mechanisms to avoid rapid destruction before getting to the target tumor. Intratumoral administration is straightforward and feasible in the indications that we have selected. The first FDA approved oncolytic virus, Imlygic, is intratumorally administered. Although approved, this agent has had modest commercial success, with annual peak worldwide sales under $100M. These commercial results can be explained by a variety of factors. First, Imlygic treatment missed the endpoint of improved survival. Second, at the time of Imlygic's approval, other successful treatments became available, such as immune check point inhibitors, and BRAF/MEK inhibitors. Third, Imlygic requires -70°C storage, which necessitates specialized and expensive equipment. CAN-2409, in contrast, is stable at 4°C, which is compatible with inexpensive storage refrigerators. In summary, CAN-2409 injection is aligned with clinical practice, can be stored at regular refrigerator temperatures, and cost of goods are expected to be low.

Our CAN-2409 Programs

Localized Prostate Cancer

Prostate cancer is the second leading cause of cancer deaths in men in the U.S., representing a high level of medical burden and unmet need. Approximately 200,000 men in the U.S. are diagnosed with prostate cancer annually, with more than 30,000 deaths each year. As shown in the chart below, of the approximately 150,000 men in the U.S. who were diagnosed in 2020 before their prostate cancer had metastasized, roughly 105,000 are considered intermediate- or high-risk of progression and approximately 45,000 are considered to be low-risk. For the intermediate- and high-risk patients, the standard of care is radical prostatectomy and radiotherapy often in conjunction with androgen deprivation therapy or chemical castration. Weighing the balance between therapeutic efficacy and side effects linked to therapy, about 10% of the intermediate-risk patients, and approximately 40% of the low-risk patients decide, in consultation with their physicians, to adopt a close monitoring approach known as active surveillance that involves periodic imaging, biomarker evaluation and biopsies.

CAN-2409 current target patient populations in localized prostate cancer

To our knowledge, the only FDA-approved pharmacologic intervention indicated for newly diagnosed localized prostate cancer is chemical castration therapy, also known as ADT. Standard of care for localized disease is primarily surgery, radiotherapy and/or ADT. Because ADT has a potentially severe side effect profile, including impotence, hot flashes, mood changes, depression and others, these hormone treatments are reserved only for those patients that present the highest risk of localized or metastatic prostate cancer. Similarly, surgical prostatectomy can often cause urinary dysfunction and sexual dysfunction that can last years and sometimes be permanent. Approximately one-third of men with normal baseline function will report some increase in urinary symptoms and urgency after prostatectomy and the majority of men will experience some erectile dysfunction after treatment with either surgery or radiation.

As a result of PSA screening programs, a majority of patients are diagnosed at early stages of disease with low grade, low volume, asymptomatic prostate cancer. Current screening methods are inadequate to definitively identify which patients are most likely to progress. As a result of these side effects, there is a large desire to delay or prevent the need for radical treatment. As a result, many men with prostate cancer meeting the National Comprehensive Cancer Network (NCCN) guidelines for low-risk prostate cancer choose not to be treated and to undergo an intense monitoring program, known as Active Surveillance (AS), as their preferred initial course of treatment. However, within 10 years of diagnosis, between 21 and 38% of men will have developed progressive cancer and require invasive treatments. It has been reported that 21 and 41% of patients initially under AS convert to active treatment based on progression of their disease within two and five years, and approximately 17% of men undergoing AS choose to move to active treatments within 10 years of diagnosis, even in the absence of any evidence of progression, underscoring the level of concern around progression and the significant unmet need in this early line of treatment.

We believe CAN-2409 provides a significant commercial opportunity for therapeutic use in the newly diagnosed, localized prostate cancer patient population, with the goal of reducing progression or recurrence of disease without significant toxicities and with a product that can be administered at outpatient facilities.

Clinical Experience with CAN-2409 for Prostate Cancer

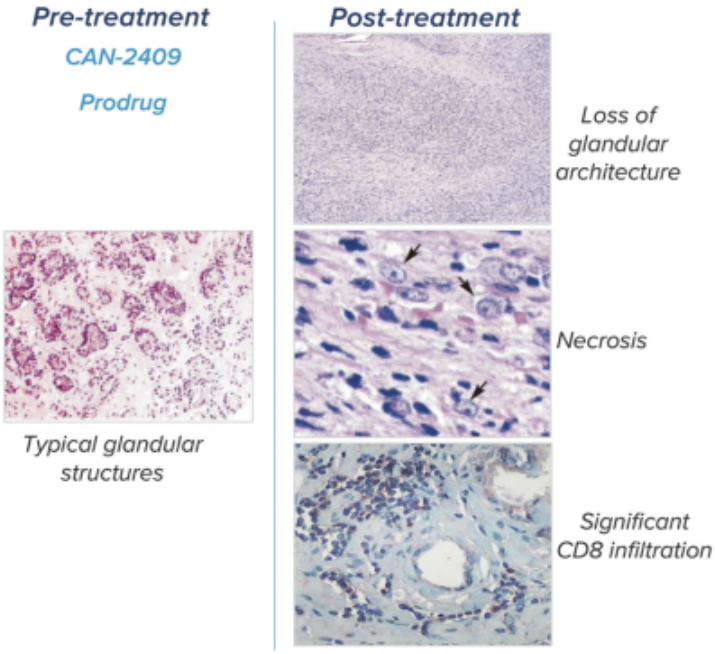
We have completed multiple Phase 1 clinical trials in non-metastatic prostate cancer using CAN-2409 as monotherapy and in combination with standard of care. The results of these trials provide evidence to support CAN-2409 immune activation, dosing levels and schedules as well as a favorable tolerability profile. We have administered CAN-2409 to over 700 patients with localized prostate cancer to date, of which approximately 500 are in currently ongoing, placebo-controlled randomized trials.

Monotherapy Activity

We have observed what we believe to be a clinical response with CAN-2409 as monotherapy in our Phase 1 trials. These responses have been observed in patients with prostate cancer, including patients with newly diagnosed, localized disease, as well as those whose cancer was progressing even after radiotherapy.

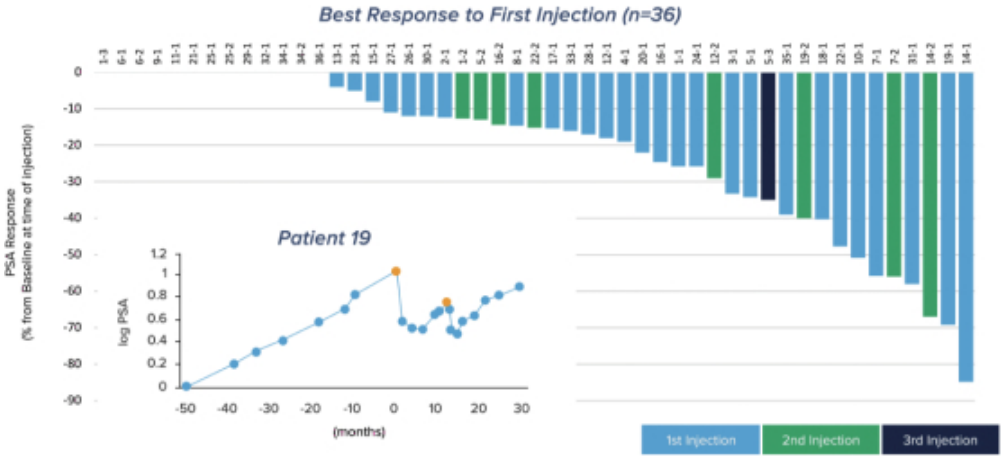
In newly diagnosed patients with localized prostate cancer, analysis of biopsies following monotherapy CAN-2409 treatment revealed change in glandular architecture, necrosis and increased immune cell infiltration as compared to baseline biopsy. We observed in treated samples a 4-fold increase in the number of CD8 positive T cells and a 3-fold increase in the number of CD68+ macrophages, demonstrating immune response to CAN-2409.

Induction of CD8+ tumor-infiltrating lymphocytes in phase 1/2 prostate cancer trial



In another of our Phase 1 trials, patients whose prostate cancer had progressed following radiotherapy and that presented a persistently rising PSA level, were treated with CAN-2409 as monotherapy using six dose levels, ranging from $1x10^{8}$–$1x\ 10^{11}$viral particles. In 27 of the 36 patients recruited, a decrease in PSA levels was observed following a single cycle of CAN-2409, as measured by the best PSA decrease in serial assessments within the first 3 months after treatment. PSA, while an imperfect biomarker for prostate cancer, is still widely employed for patient management in conjunction with biopsy, as rising PSA levels, and in particular PSA doubling time are associated with disease progression. In that same trial, we observed that the PSA doubling time improved significantly (p=0.0271) from 15.9 months at baseline to 42.5 months after a single cycle of CAN-2409 administration, in this treatment resistant patient population. A subset of the patients in this trial also received second or third injection courses of CAN-2409. In the majority of those patients, a decrease from pre-administration PSA levels was again observed upon repeated injection. This dynamic is illustrated below in the inset PSA graph of “patient 19” in this trial. The orange datapoints represent PSA levels immediately prior to CAN-2409 administration. After a first dose, the patient’s PSA level dropped below baseline levels for over 10 months at which point serial increases were observed, as expected in recurrent prostate cancer. Upon a second injection course of CAN-2409, a sequential drop in PSA was again induced, indicating potentially repeated CAN-2409 activity even in recurrent disease subsequent to an initial response.

Best Response to First Injection (n=36)



Use of CAN-2409 in Combination Therapy

Because of the increasing prevalence of combination therapy for cancer patients, the ability to combine novel agents with standard of care treatments without overlapping toxicity is of increasing importance. We believe that the favorable tolerability profile of CAN-2409 demonstrated in our clinical trials is encouraging for our current and future development plans, in combination with other agents but also as a monotherapy in lower risk patient populations that are not willing to undergo more aggressive forms of treatment. The safety data from our Phase 2 clinical trial in prostate cancer patients treated with CAN-2409 in combination with standard of care are summarized in the table below. Of note is the absence of reported grade 4 treatment related adverse events and only single-patient incidence of grade 3 treatment related adverse events. It was anticipated that flu-like symptoms would be evident, because CAN-2409 is an adenoviral gene construct known to induce a systemic immune response. Greater than 50% of patients reported fever and/or chills often associated with viral immune activation. These symptoms, which generally manifested early and transiently, often occurred on the evening of the intratumoral administration of CAN-2409 and resolved by the following morning. The rates of the gastrointestinal adverse events are consistent with those typically reported by patients undergoing radiotherapy, which is a component of standard of care in this population.

Phase 2 prostate cancer safety data for prostate cancer patients treated with CAN-2409 in combination with standard of care

N=71	Gr 1 (%)	Gr 2 (%)	Gr 3 (%)	Gr 4 (%)
Laboratory by CTC criteria				
Leukopenia	49%	9%	0%	0%
Anemia	94%	0%	0%	0%
Thrombocytopenia	54%	0%	0%	0%
AST, ALT or GGT increase	49%	7%	1%	0%
ALP increase	21%	0%	0%	0%
Hyperbilirubinemia	12%	0%	0%	0%
LDH elevation	46%	0%	0%	0%
Creatinine elevation	16%	0%	0%	0%
Symptoms by CTC criteria				
Allergy	1%	0%	0%	0%
Fatigue	33%	1%	0%	0%
Fever	28%	4%	0%	0%
Rigors	53%	0%	0%	0%
GU/GI by RTOG criteria				
Acute Genitourinary	31%	51%	1%	0%
Late Genitourinary	30%	17%	1%	0%
Acute Lower Gastrointestinal	20%	24%	0%	0%
Late Gastrointestinal	13%	9%	0%	0%

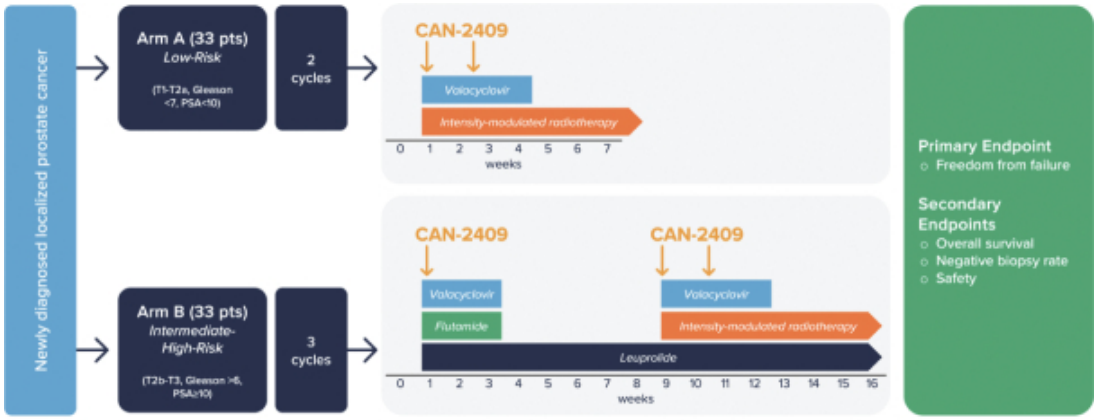
Few Grade 3 events, no Grade 4

Typical viral vector-induced short-term, low grade flu-like symptoms

GU/GI side effects comparable to radiotherapy alone

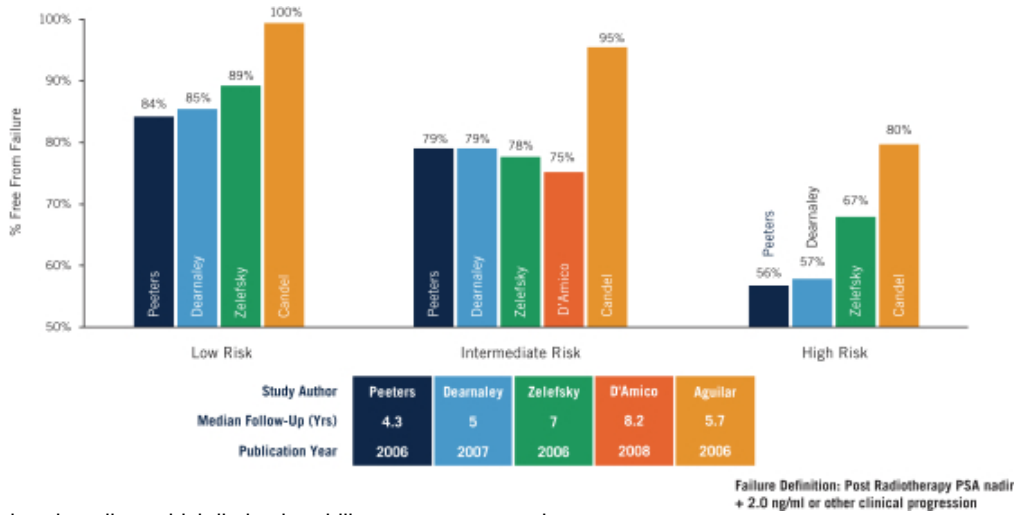
Our Phase 2 trial data informed our agreement with the FDA under the SPA for our ongoing Phase 3 clinical trial. In our Phase 2 clinical trial, we observed that intermediate-risk patients who received CAN-2409 in combination with radiotherapy had failure rates that were 75% lower than those reported in four other contemporaneous trials of similar patient populations as shown in the table below, although this is limited because we have not conducted head-to-head studies. Where these other clinical trials reported freedom from failure rates of between 75-79%, corresponding to cumulative recurrence rates of 21-25%, CAN-2409 resulted in a 5% recurrence rate in patients with intermediate-risk prostate cancer. The median follow-up for the clinical trial of CAN-2409 was 5.7 years. Similarly, results in this clinical trial also demonstrated reduced recurrence rates in the low- and high-risk patients enrolled when compared to these other trials. Furthermore, a pathological complete response (pCR) was observed in 93% of the biopsies available at 2yrs (37%-73% in control populations). In this trial, low-risk patients achieved a PSA of < 2ng/ml in 77% of CAN-2409 treated patients versus 58% in control populations. The schema for this trial is shown below.

Completed phase 2 clinical trial of CAN-2409 combined with radiotherapy +/- androgen deprivation therapy



Failure was measured from the start date of treatment until the date of treatment failure defined as clinical failure or biochemical failure, whichever first, according to the Phoenix ASTRO consensus (Nadir +2)

Freedom from failure in varying risk populations of localized prostate cancer



Failure Definition: Post Radiotherapy PSA nadir + 2.0 ng/ml or other clinical progression

These were not head-to-head studies, which limits the ability to compare results.

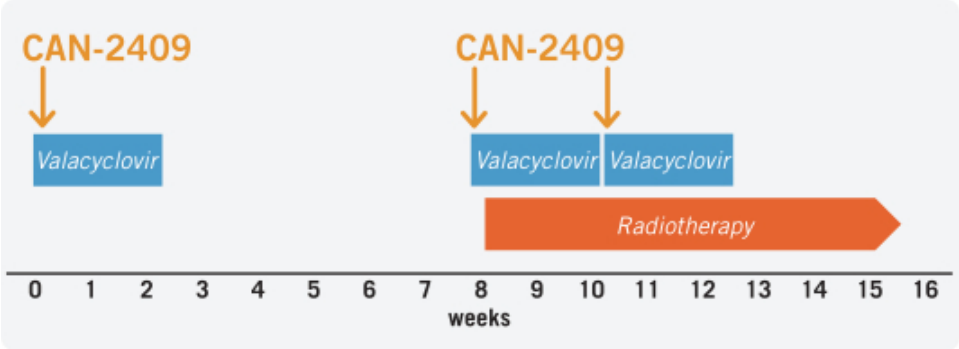
The endpoint used in our Phase 2 trial is freedom from failure (FFF), defined by the period of time between treatment and the occurrence of a clinical or biochemical failure. Under the SPA agreement, we have selected disease-free survival (DFS) as the endpoint for our Phase 3 clinical trial. The DFS definition requires an objective detection of tumor progression. This largely overlaps with FFF as it is often triggered by detection of an increased PSA levels (i.e., biochemical failure). We have also reanalyzed our Phase 2 data using DFS parameters, supporting the implementation of DFS as endpoint in our Phase 3 trial.

Our Pivotal Phase 3 Clinical Trial for Localized Prostate Cancer

We are developing CAN-2409 as a potential therapeutic option that avoids the long-term severe side effects of hormone therapy or surgical interventions. Based on the data from our clinical trials to date, we believe that CAN-2409 has the potential, if approved, to be the first product candidate approved for patients with localized prostate cancer in over 30 years. We are currently conducting a Phase 3 trial for CAN-2409, with agreement, under an SPA with the FDA for a single pivotal trial in newly diagnosed localized prostate cancer in intermediate and high-risk patients in combination with the standard of care, radiotherapy.

The clinical trial is evaluating 711 patients, randomized 2:1. Patients will receive three investigational treatment courses of CAN-2409, each consisting of four concurrent injections of transrectal ultrasound guided administration of CAN-2409 followed by a course of oral valacyclovir. As illustrated schematically below, the first injection course is given at least 15 days but not more than 8 weeks before starting radiation. The second injection course is given 0-3 days prior to radiotherapy. The third and final injection course is delivered 15-22 days after the second injections. A fixed dose of valacyclovir is given for 14 days after each injection course. Standard of care external beam radiotherapy will be administered to patients throughout the course of the trial with optional ADT as determined by the treating physician.

Dosing scheme for CAN-2409 Phase 3 prostate cancer trial



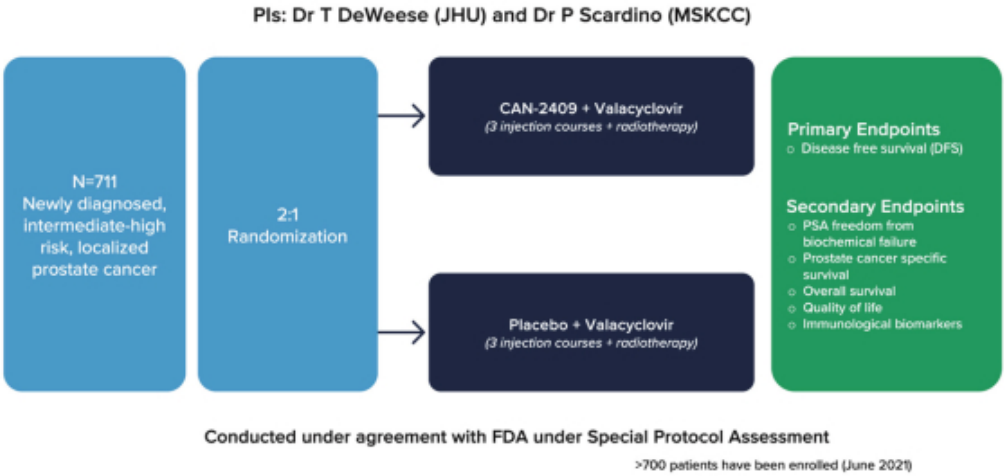
Trial inclusion criteria are based on patients with localized prostate cancer meeting the NCCN criteria of intermediate-risk or patients presenting only one NCCN high-risk feature. NCCN intermediate-risk is defined as having at least one of the following: prostate serum antigen (PSA) of 10-20 ng/ml, Gleason Score of 7, and is staged T2b-T2c via the TNM staging system. Patients may also exhibit one high-risk characteristic that may consist of a PSA of 20+ ng/ml, a Gleason Score of 8-10, or a cancer that is up to stage T3a, but not more than one of these high-risk factors.

Our SPA agreement indicates concurrence by the FDA that specific critical elements of the design and size of our Phase 3 trial are adequate to support future regulatory approval if, among other things, we achieve the primary endpoint in the trial. We have approximately 50 active clinical sites enrolling patients for this clinical trial, have enrolled over 700 patients and anticipate completing enrollment in the third quarter of 2021.

The primary endpoint for the clinical trial is DFS. Final results are expected in 2024. This trial has been designed to have 90% power, a hazard ratio of 0.5 and an alpha of 0.05. We are assuming a 15% improvement in the active arm (CAN-2409) as compared to placebo in the rate of events measured according to the DFS definition provided above.

A schema of this trial is set forth below.

Ongoing Phase 3 clinical trial of CAN-2409 in newly diagnosed, intermediate- and high-risk prostate cancer

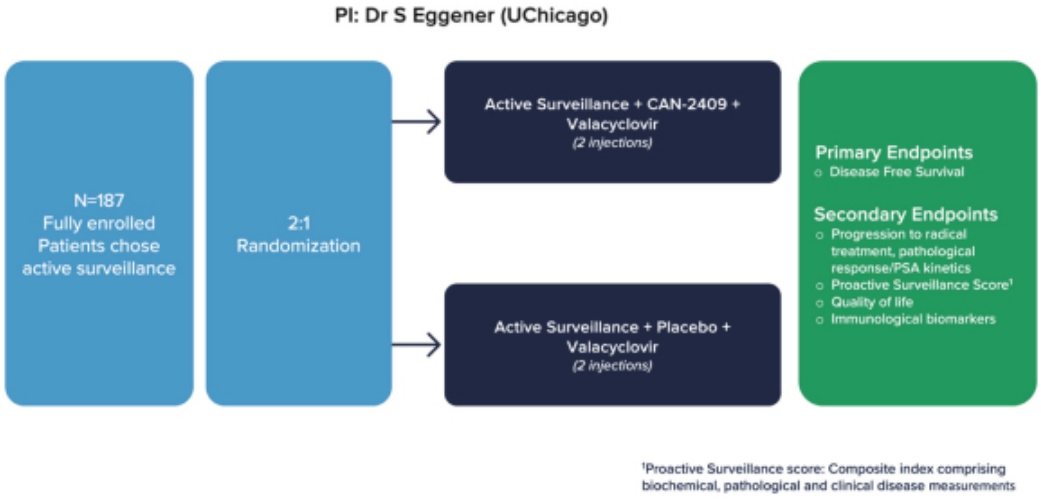


Phase 2 Clinical Trial for Active Surveillance

Clinical results to date suggest that CAN-2409 as monotherapy may reduce the rates of biochemical failure for patients with localized prostate cancer. In the AS setting, we will assess whether CAN-2409 has the potential to delay or prevent tumor progression to a later stage that demands radical treatment.

The Phase 2 clinical trial is a randomized, double blind, placebo-controlled study evaluating 187 patients with localized prostate cancer undergoing AS. The trial completed enrollment in June 2019. Patients in this clinical trial were randomized 2:1, active to placebo. Patients randomized to the active arm received two investigational treatment courses of CAN-2409. The primary endpoint will assess patients' risk of progression employing validated endpoints. We expect top line data from this clinical trial to be available in 2023. A schema of this trial is set forth below.

Fully accrued ongoing Phase 2 clinical trial of CAN-2409 in patients with prostate cancer being managed by active surveillance



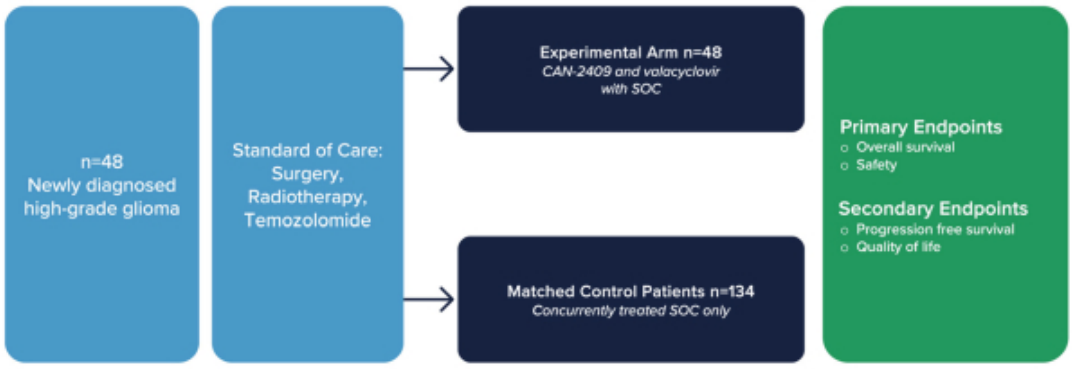
High-Grade Glioma

Glioblastoma, the most common form of high-grade glioma, is a relatively rare cancer with first-line drug treated prevalent population in the U.S. of approximately 16,113 patients. In second- and third-line this number drops to 11,642 and 6,548, respectively. Fewer than 10% of patients survive more than 5 years past their initial diagnosis. The median survival is under 15 months with the current standard of care. Treatment in the upfront setting is surgical resection, if possible, coupled with temozolomide and/or radiotherapy. Over half of patients are candidates for maximal surgical resection and a portion succeed, achieving removal of all visible tumor mass. This outcome is known as gross total resection. Few pharmaceutical treatment options exist for patients with high-grade glioma, with the last significant FDA approval over a decade ago. Avastin was approved in 2009, specifically for patients with recurrent glioblastoma, and approval was granted despite the absence of a survival benefit in the registrational studies. Temozolomide was approved over 20 years ago, in 1999, with no new agent significantly supplanting its use since then, further underscoring the profound unmet medical need in this condition. In the registrational clinical trials, temozolomide use only demonstrated 2.5-month overall survival benefit, yet still saw global annual sales of over $1 billion at its peak in 2010, shortly before generic products entered the market. The prognosis for glioblastoma that has recurred is even more dire. Patients have scarce treatment options. Current standard of care mainly consists of repeating first line treatment approaches or participating in a clinical trial of investigational agents. Median survival in the recurrent setting is approximately six months.

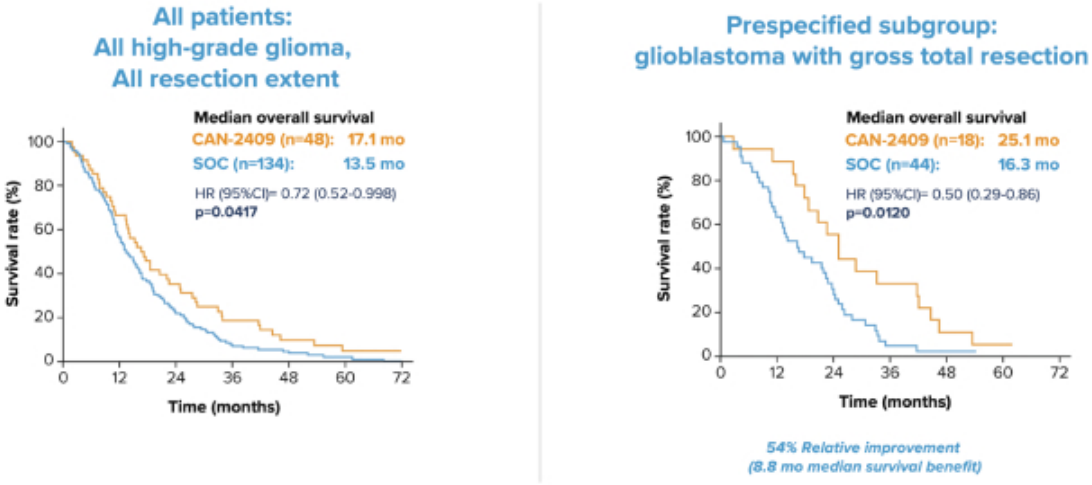
CAN-2409 for High-Grade Glioma

In our Phase 1b/2 clinical trial in newly diagnosed patients with high-grade gliomas, including the difficult-to-treat glioblastoma, CAN-2409 demonstrated a statistically significant increase in patient survival when combined with current standard of care over the current standard of care alone (surgery, radiation and temozolomide). The trial compared the overall survival of 48 enrolled patients treated at 4 clinical sites with CAN-2409 plus standard of care against a matched controlled set of 134 patients enrolled at Mass General Brigham who received only standard of care. The results demonstrated that the median overall survival of patients receiving standard of care alone was 13.5 months while patients receiving CAN-2409 plus standard of care was 17.1 months (p=0.0417) (left panel in the figure below). Importantly, a pre-planned analysis on a subset of patients treated surgically with gross total resection (>95% of tumor removed) during surgery (18 patients compared with 44 in the control arm), demonstrated a median overall survival of 25.1 months in the CAN-2409 arm versus 16.3 months in the standard of care group, with approximately a 50% improvement (p=0.0120) (right panel in the figure below). In this patient population, after three years, 1 in 3 patients was alive in the CAN-2409 arm compared to 1 in 20 patients in the standard of care group. At the end of the study, three of the patients who received CAN-2409 were alive without progression at 43, 62.1 and 88.5 months of follow up.

Completed phase 1b/2 clinical trial of CAN-2409 combined with standard of care in high-grade glioma



CAN-2409 +SOC



In our Phase 1/2 trials in high-grade glioma, CAN-2409 was generally well tolerated, with the majority of treatment-related adverse events being Grade 1 or 2, with few reports of Grade 3 or 4 events.

Treatment Related Adverse Events from Phase 1/2 High-Grade Glioma

	0-3 weeks (n=56)				4-8 weeks (n=53)		
	Gr 1	Gr 2	Gr 3	Gr 4	Gr 1	Gr 2	Gr 3
Constitutional Symptoms							
Fatigue	1	1				2	
Fever	3	2					
Insomnia	1		1				
Dermatology							
Wound Complication							1
Gastrointestinal							
Vomiting		2					
Neurology							
Mood alteration- Depression	1				1	1	
Neuropathy – Motor		1		1			
Speech Impairment			1				
Pain							
Headache	2	1	1		2	1	

Adverse events deemed possibly related to AdV-tk or valacyclovir
and occurring in >1 pt in a time period or any incidence of Common Terminology Criteria grade 3 or 4

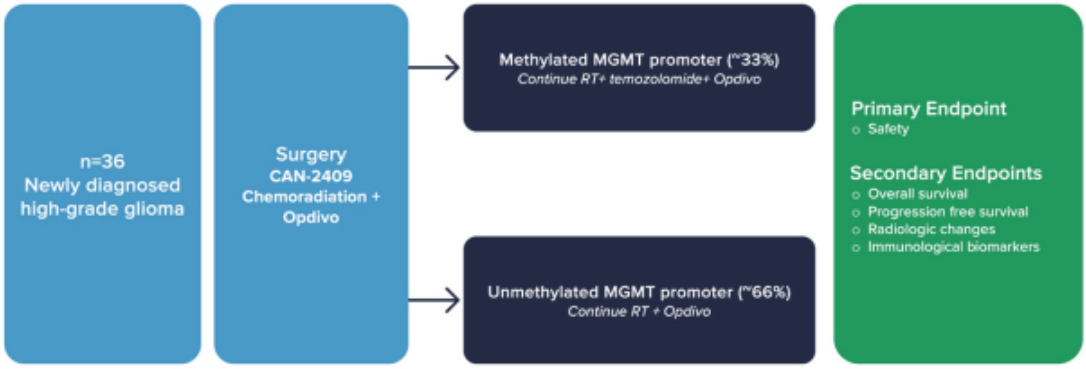
We are planning a potentially registrational Phase 3 clinical trial in patients with untreated high-grade glioma. The current trial design for this Phase 3 is an adaptive trial design, enrolling patients with glioblastoma (WHO Grade IV) intended to undergo gross total resection and standard of care chemoradiation. The primary efficacy endpoint will be overall survival, powered to 90% with a hazard ratio of 0.65 and a type I error assumption of 2.5. We anticipate the trial to commence in the first half of 2022.

CAN-2409 Checkpoint Combination Therapy for High-Grade Glioma

Based on the clinical outcomes in glioma patients treated with CAN-2409 and the biomarker evidence for CAN-2409-mediated immune stimulation, we performed preclinical studies to examine whether CAN-2409 treatment of high-grade glioma would be enhanced if combined with immune checkpoint inhibitors to increase antitumor T cell responses. Use of either an anti-PD-1 antibody or CAN-2409 alone resulted in 30%-50% long-term survival in a murine glioma model. This percentage increased to 88% when CAN-2409 and anti-PD-1 were administered together. Analysis of infiltrating T cells indicated that CAN-2409 increases the activation of tumor-infiltrating CD8+ T cells, suggesting that the activity of this combination is due to a complementary biological mechanism of the two treatment modalities.

A Phase 1 clinical trial for patients with newly diagnosed high-grade glioma examining the combination of CAN-2409 and anti-PD-1 nivolumab (Opdivo, BMS) in collaboration with BMS and ABTC has now completed enrollment. This is the first clinical trial to evaluate the combination of CAN-2409 and nivolumab in high-grade glioma patients. Combining CAN-2409 with an ICI such as anti-PD-1 may enhance anti-tumor T cell activation and expansion, with the potential for better clinical outcome.

Ongoing Phase 1 clinical trial of CAN-2409 with Opdivo in high-grade glioma



Oncolytic Viral Immunotherapy in High-Grade Glioma

Oncolytic viral immunotherapy is a description of a therapeutic modality that encompasses multiple different constructs and divergent pharmacologic strategies. Some other viral approaches in high-grade glioma have previously failed, notably the investigational oncolytic viral immunotherapy agent Toca 511 that was evaluated in a Phase 2/3 trial in glioblastoma conducted by the company Tocagen. In the case of Toca 511, we believe the similarities to CAN-2409 in glioblastoma are very limited. Toca 511 was a retroviral construct that used a different transgene, was paired with a different prodrug, and had a different development program. There are significant differences between the programs. Of note, serotype 5 adenoviral gene constructs like CAN-2409 have been demonstrated to be highly immunogenic, whereas retroviruses are less immunogenic and therefore less likely to induce a strong innate immune response. Critically, in the single arm Phase 1 trial of Toca 511 in glioblastoma, the data from the investigational agent was compared to a non-concurrently treated external control group that was poorly matched to the demographics of the investigational cohort. For example, 74% of patients in the Toca 511 cohort had a Karnofsky performance score greater than 90, whereas only 51% of patients in the comparator group had such good clinical baseline status. The result was a (false) positive comparison in the Phase 1 trial in favor of the Toca 511 treated group. Further complicating interpretation of the Phase 2/3 trial, patients received only a median of two courses of prodrug commencing 6 weeks after virus dosing. With such significant differences between programs and in the conduct of clinical trials, we believe that such failures of other oncolytic viral immunotherapies in high-grade glioma and other indications have limited bearing on the probability of success of the Phase 3 trial of CAN-2409 in glioblastoma.

Additional Solid Tumor Opportunities

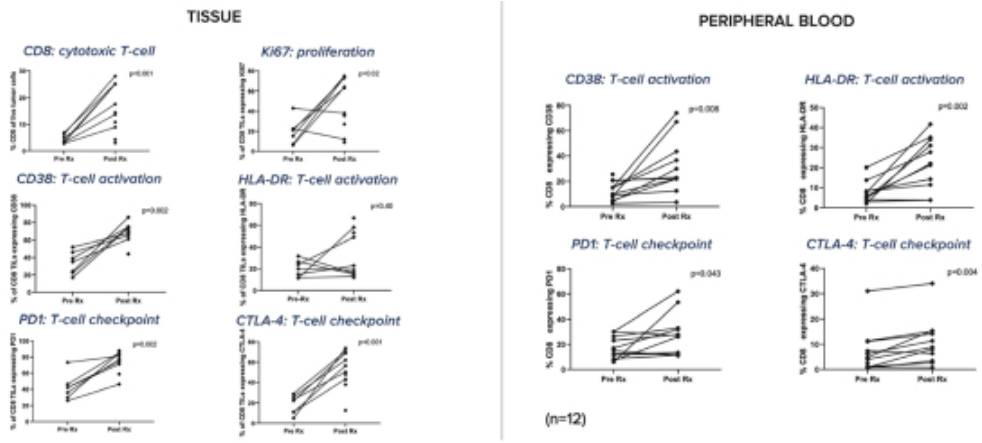
Lung Cancer (NSCLC)

In recent years, immune checkpoint inhibitors, specifically PD-1 directed agents, have transformed the treatment paradigm of NSCLC and become a backbone therapy for this indication. To date, seven immune checkpoint inhibitor products have been approved in a number of cancer indications, and there are numerous other related drug

candidates in preclinical and clinical development. Global sales for ICIs in 2019 were approximately $23 billion with NSCLC, accounting for between 50 and 55% of overall sales. The commercial opportunity in NSCLC is significant. Drug treated patient populations in the US for 2020 are estimated at 75,160; 47,920 and 21,990 in first-, second- and third-line treatment, respectively. ICI use in NSCLC has become standard of care with approximately 49% of first-line patients in the US being treated with an ICI alone or in combination with other agents. Nonetheless, the median overall survival is approximately 22 months.

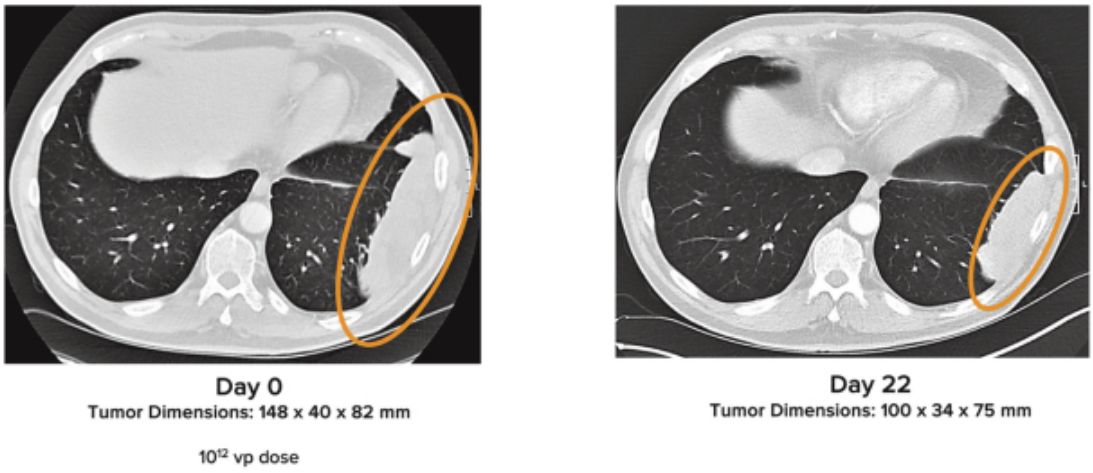
To assess the potential for CAN-2409 to trigger immune activation and produce a “hot” tumor phenotype, we designed and completed a clinical trial in patients with surgically resectable lung cancer. In this Phase 1 trial, dose escalation of intratumoral neoadjuvant CAN-2409 was followed by tumor resection three weeks later. The specific goal was to obtain biological data to better understand the impact of CAN-2409 on the tumor microenvironment, with a specific focus on intratumoral CD8+ T cell activation and function while assessing effects on the systemic immune response. The effects of CAN-2409 were evaluated by comparing post-injection specimens to an internal control consisting of each patient’s own pre-treatment needle biopsy and blood samples, and an external cohort of matched patients who underwent standard surgical resection without CAN-2409. The results showed evidence of significant intratumoral and systemic immune activation. Selected analyses are set forth in the chart below. Analysis of peripheral blood mononuclear cells, both before and after CAN-2409 administration, demonstrate a significant increase in expression of proliferation and activation markers including HLA-DR, CD38 and Ki67 three weeks after CAN-2409 initiation. Other relevant findings in this clinical trial included an increase in some markers of T cell activation such as PD-1 and CTLA-4, which are targets of immune checkpoint inhibitors that have been approved for use in NSCLC.

CAN-2409 treatment stimulates local and systemic T cell response



In our NSCLC Phase 1 clinical trial, two patients experienced grade 3 dehydration with renal insufficiency, two patients presented grade 3 urinary retention and six patients were observed to have a grade 4 low lymphocyte count. Of significant interest, one patient, a 70 year old male with a 14.8cm stage IIIA sarcomatoid carcinoma, exhibited a nearly 50% decrease in tumor volume at 3 weeks after CAN-2409 monotherapy treatment. Scans from this patient are shown below. Collectively, these results lead us to believe that CAN-2409 could provide an opportunity to improve ICI response rates in patients with NSCLC by eliciting additional immune activation in lung cancer patients.

Monotherapy activity of CAN-2409 in NSCLC

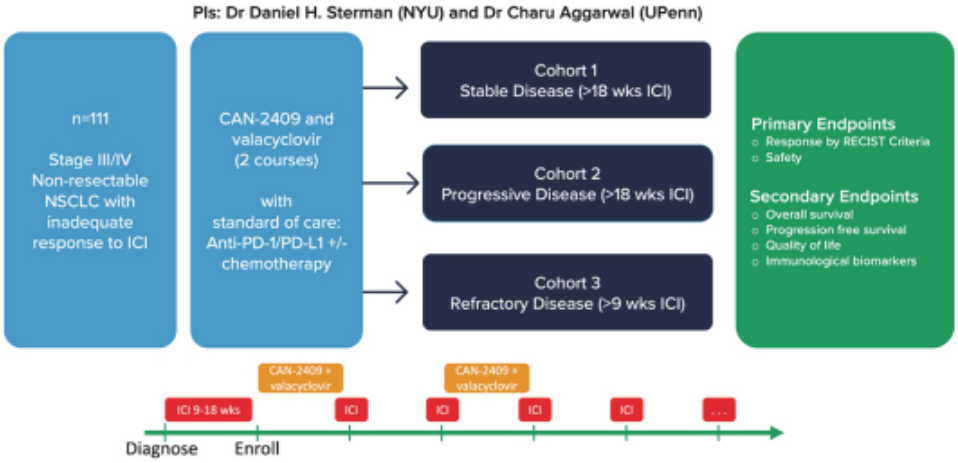


CAN-2409 and Checkpoint Combination Phase 2 Clinical Trial for NSCLC in Patients with Inadequate Response to ICI

We have initiated a Phase 2 clinical trial in NSCLC patients with inadequate response to ICI that will enroll patients receiving standard of care immune checkpoint inhibitors (plus chemotherapy if indicated) across three cohorts in combination with two courses of CAN-2409 plus ICI. We believe there is an opportunity to utilize CAN-2409 immune activation to improve ICI response rates with a short-term readout.

Our open label Phase 2 trial will enroll 111 patients and we expect initial safety data, translational biomarkers and efficacy data to be presented in the first half of 2022. The trial schema is set forth below.

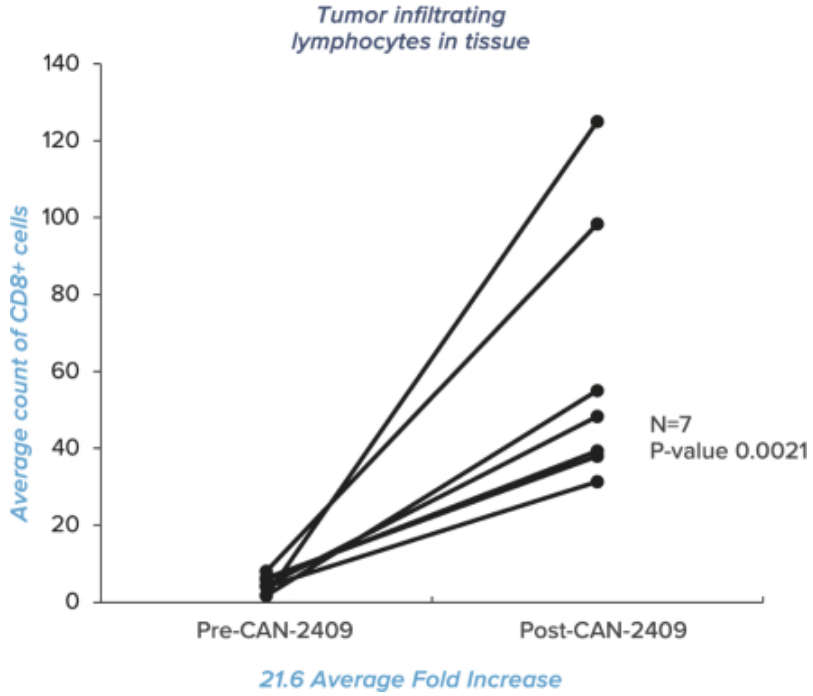
Ongoing Phase 2 trial of CAN-2409 plus immune checkpoint inhibitor (ICI) and standard of care (SOC) chemotherapy for stage III/IV NSCLC Patients



Pancreatic Cancer

We are currently conducting an exploratory Phase 2 clinical trial for CAN-2409 in pancreatic cancer, with enrollment ongoing. We anticipate presenting interim data in 2023. In a previous Phase 1b trial, patients with pancreatic cancer treated with CAN-2409 in addition to standard of care demonstrated a greater survival duration over the expected survival of the patients treated with the existing standard of care alone in a comparison to historical trial results. Furthermore, in a number of patients where pre- and post-treatment tumor biopsies were available, a statistically significant increase in the number of CD8+ tumor infiltrating lymphocytes was observed. In addition, the study concluded that CAN-2409 was generally well-tolerated in combination with standard of care.

CAN-2409 Induction of CD8+ tumor-infiltrating



Other Cancer Indications

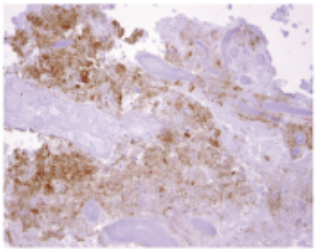
In addition to patients with prostate, brain, lung and pancreatic cancer, CAN-2409 has been dosed in small early-stage exploratory clinical trials in patients with ovarian cancer, malignant pleural effusion, pediatric brain cancer and retinoblastoma, supporting the tolerability profile described above.

Our CAN-3110 Program: Recurrent Glioma

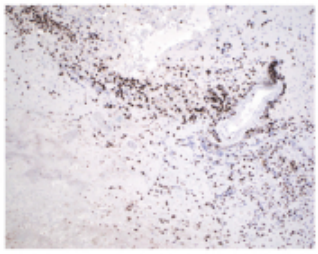
Our first HSV-based program, CAN-3110, is now in a Phase 1 clinical trial in recurrent glioblastoma with additional data expected in the fourth quarter of 2021. This clinical trial is assessing CAN-3110 and is an open-label, single center, dose-escalation clinical trial. The primary endpoint of this clinical trial is to analyze the safety of CAN-3110 use, in patients with recurrent high-grade glioma. No dose-limiting toxicities were observed in doses ranging from $1x10^6$ to $1x10^{10}$ PFU in half-log increments. 30 patients have been treated in the initial dose escalation phase and 12 additional patients had been dosed in a dose expansion phase as of April 30, 2021.

Immunohistologic studies showed persistent presence of HSV antigen and infiltration by $CD8^+$ cytotoxic tumor infiltrating lymphocytes post treatment, providing support for the expected mechanism of action of CAN-3110.

Oncolytic HSV infection and CD8+ T cell infiltration after CAN-3110 treatment in patients with recurrent high-grade glioma



HSV1 antigen 6 weeks after injection of $1x10^6$ pfu
1.79×10^6 copies of viral DNA/mg
2.97×10^5 copies of viral RNA transcript (ICP22)/mg

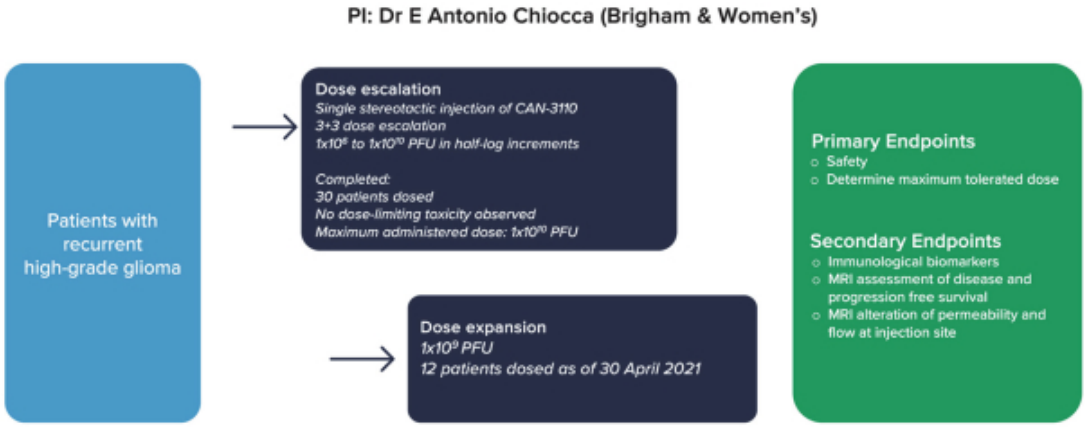


Infiltration by CD8+ cytotoxic T cells
(tumor infiltrating lymphocytes)

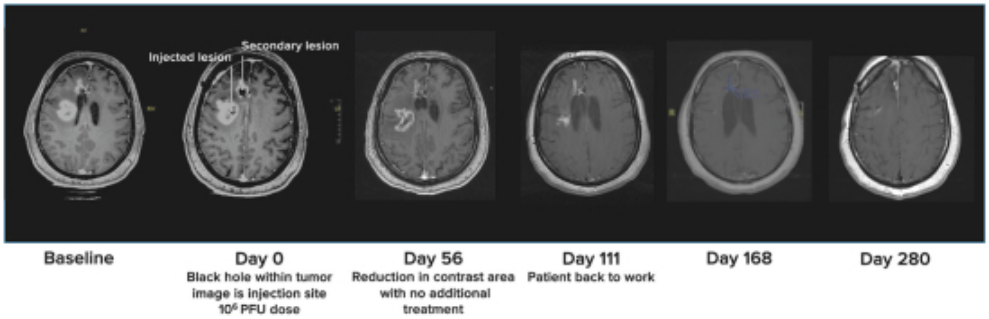
Post-treatment tissue (available in 18 patients) demonstrates persistence of HSV antigen and CD8+ T cell infiltrates
T cell receptor repertoire, transcriptomics, and single cell RNA sequencing analyses are ongoing

We are particularly encouraged by the clinical course of a patient who received CAN-3110 as a monotherapy upon recurrence of glioblastoma. The patient was diagnosed with multicentric glioblastoma and initially treated with standard of care surgical resection followed by temozolomide and radiotherapy. The patient later recurred with two lesions visualized on MRI. One, in the frontal region, was at the site of the initially resected mass and is labelled “Secondary lesion” in the MRI images below. The second, larger mass was a new lesion and is labeled as “Injected lesion” in the MRI images below. The patient received CAN-3110 via stereotactic administration into the injected lesion. At day 56 post-injection, there was a visible decrease in the volume of both masses. By day 112 post-injection, the volume of both masses was further reduced and the patient was able to go back to work. The patient eventually developed a third tumor and, following a stroke secondary to a diagnostic procedure, refused further treatment, dying approximately 15 months after participation in the trial. We find this to be an encouraging case report because of the unusually favorable disease course experienced by this patient in absence of concurrent therapies. Additionally, we have observed a median overall survival of 11.7 months in our Phase 1 trial in the first 30 patients as of the cutoff date of April 21, 2021. Given the median overall survival of 6-9 months in historical clinical trials of other investigational agents in patients with recurrent high grade glioma, we believe this is encouraging evidence of clinical activity. We will continue to assess CAN-3110 in this clinical trial and anticipate reporting additional data from this open label trial in the fourth quarter of 2021.

Ongoing Phase 1 clinical trial of CAN-3110 in patients with recurrent high-grade glioma



MRI images of patient from Phase 1 high-grade glioma trial of CAN-3110 with abscopal effect



Clinical effect on injected and uninjected lesions.
56 YOM, IDH wild-type, MGMT partially methylated, right frontal mesial lesion initially treated with gross total resection, chemoradiation. Recurrences at two sites.

This trial is complementary to our work in the first line treatment setting of high-grade glioma with CAN-2409, a non-replicating viral construct. We believe that with the larger tumor burden frequently observed in the recurrent setting and more infrequent use of surgery in this population, a replication competent viral construct such as CAN-3110 may be a more appropriate approach.

Collaborations and Other Transactions

We are a party to a number of license and collaboration agreements under which we license patents, patent applications and other intellectual property to and from third parties. These licenses impose various diligence and financial payment obligations on us. We expect to continue to enter into these types of license agreements in the future. We consider the following license and collaboration agreements to be material to our business:

Periphagen. On December 9, 2019, we entered into a series of agreements, including an exclusive license agreement, a novation agreement, an equipment purchase agreement and an intellectual property assignment agreement, collectively the Periphagen Agreements, with Periphagen, whereby we acquired certain assets and licensed certain rights (including specified patent rights and know-how, or the Licensed IP Rights) of Periphagen, primarily consisting of exclusive rights to their technology platform and a portfolio of pre-clinical, development stage virus vectors, as well as certain physical property and equipment. The primary classes of assets are HSV-derived assets expressing neurotrophin-3 (or NT-3 Assets) and other HSV-derived assets (Gene Transfer Neuro-Assets). Under the license agreement, Periphagen granted us a worldwide exclusive license with the right to grant sublicenses through multiple tiers under the Licensed IP Rights to conduct research and to develop, make, have made, use, have used, offer for sale, have sold, export and import products incorporating the Licensed IP Rights in all fields of use except the treatment, diagnosis, and prevention of nononcologic skin diseases and conditions (including use as an aesthetic).

In addition, pursuant to the Periphagen Agreements, we undertook certain commitments and obligations, including the assumption of Periphagen's outstanding loan in the principal amount of $1,000,000 with Diamyd Medical, AB. The promissory note has a contractual interest rate of 2% compounded annually, with the outstanding balance and accrued interest due upon maturity in November 2027, with no interim installments.

In consideration for the licenses under the Periphagen Agreements, we paid Periphagen $811,000 upon signing and agreed to make the following royalty and other payments:

- NT-3 Assets: a single digit percentage of net sales of NT-3 Assets, or, if applicable, a percentage of royalties received by us in the event of a license, sublicense, assignment or other transfer to a third party for commercialization (but no greater than the original royalty percentage we would be required to pay in the event we did not license, sublicense, assign or transfer NT-3 Assets);
- Gene Transfer Neuro-Assets: a single digit percentage of net sales of Gene Transfer Neuro-Assets, or, if applicable, a percentage of royalties received by us in the event of a license, sublicense, assignment or

other transfer to a third party for commercialization to treat certain conditions and diseases (but no greater than the original royalty percentage we would be required to pay in the event we did not license, sublicense, assign or transfer Gene Transfer Neuro-Assets);

- Combination Products: a certain percentage (based on the weighted average sale price of NT-3 Assets, or Gene Transfer Neuro-Assets, as applicable) of net sales of combination products; and
- Disposition Income: (i) a single digit royalty rate of certain consideration we receive for the grant of a license, assignment or other intellectual property rights related to the NT-3 Assets and (ii) if we consummate a strategic collaboration with certain specified parties to treat non-oncolygic neurological conditions and diseases, either 2nd decile (if consummated within 18 months) or mid-2nd decile to mid-3rd decile (if consummated thereafter) royalty rates of certain consideration we receive for the grant of a license, assignment or other intellectual property rights related to the Gene Transfer Neuro-Assets.

If we are required to pay royalties to a third party on any product covered under the Periphagen Agreements, we may credit such royalty payments against the royalties owed to Periphagen in the applicable country, up to a percentage reduction in the mid-2nd decile.

The exclusive license agreement with Periphagen, or the Periphagen License Agreement, requires us to use commercially reasonable efforts to complete a human proof of concept clinical trial of an NT-3 Asset, which includes certain specified clinical milestones. If we fail to use such efforts, subject to dispute and escalation provisions in the Periphagen License Agreement, then we may submit a specified payment in lieu of satisfying such obligations. If we fail to do so, Periphagen may terminate the Periphagen License Agreement for material breach.

The Periphagen License Agreement expires on the later of December 9, 2069 or the end of the Royalty Term. Upon expiration, we will have a fully paid-up, non-exclusive license to make, use, sell, offer for sale and import any products that incorporate the Licensed IP Rights. The Royalty Term means, on a product-by-product and country-by-country basis, the period starting on the first commercial sale of such product in such country and concluding on the later of (i) expiration of patent coverage under the Licensed IP Rights or regulatory exclusivity for such product in such country; or (ii) the date that a certain amount of generic competition exists in such country, provided that no Royalty Term shall exceed 30 years.

The Periphagen License Agreement may be terminated (i) by us for convenience upon 90 days' prior written notice to Periphagen, (ii) by Periphagen if we remain in breach of the Periphagen Agreement following a cure period to remedy the breach or (iii) by Periphagen if we become bankrupt, file for bankruptcy or otherwise become insolvent or are placed in receivership.

BWH. On January 20, 2018, we entered into an exclusive option agreement, or the Option Agreement, with BWH. Pursuant to the Option Agreement, we obtained the exclusive right from BWH to negotiate an exclusive worldwide, royalty-bearing license to develop and commercialize products covered by certain BWH patents, including those patents covering CAN-3110, in the field of gene therapy and oncolytic vector therapy for the treatment or prevention of cancerous tumors in humans or animals, as such field is further detailed in the Option Agreement, or the Licensed Field. In consideration for BWH's granting of the exclusive option, we paid BWH a non-refundable fee of $40,000.

Under the Option Agreement, we were required to use reasonable efforts to enter into a clinical trial agreement with BWH. We entered into such clinical trial agreement with BWH, or the BWH Clinical Trial Agreement, on June 19, 2018. Under the BWH Clinical Trial Agreement, we have committed to remitting up to $750,000 for the performance of a specified Phase 1 clinical trial by BWH pursuant to a protocol summary contained in the Option Agreement.

On September 15, 2020, we exercised our option and entered into an exclusive patent license agreement with BWH, or the BWH License Agreement. Under the BWH License Agreement, BWH granted to us (a) an exclusive, royalty-bearing license under certain of BWH's patents to make, have made, use, have used, sell and have sold certain products covered by such licensed patents, or the Licensed Products and otherwise practice processes covered by such licensed patents, or Licensed Processes; and (b) a non-exclusive, royalty-bearing license under

certain other of BWH's patents to make, have made, use, have used, sell and have sold Licensed Products, but not to sell or have sold Licensed Processes. The foregoing rights are sublicensable, subject to sublicensing terms set forth in the BWH License Agreement. In connection with executing the BWH License Agreement, we paid a license issue fee of $100,000. We also agreed to reimburse BWH for all reasonable fees and expenses BWH had incurred and will incur for the preparation, filing, prosecution and maintenance of the licensed patent rights, in an amount equal to $141,268.

Under the BWH License Agreement, we are required to use commercially reasonable efforts to develop and make available to the public Licensed Products in the Licensed Field, which efforts include certain milestones detailed in the BWH License Agreement.

Under the BWH License Agreement, prior to the first commercial sale of the Licensed Products, we are required to pay BWH an annual license fee beginning on the fourth anniversary of the effective date. Following the first commercial sale of the Licensed Products, we are required to pay BWH an annual minimum royalty, which amount may be credited against earned royalties starting in the fourth year following the first commercial sale.

In addition to such annual license fee and royalty obligations, the BWH License Agreement contains cumulative milestone payments for up to a maximum amount of $39,000,000, upon the achievement of various clinical, commercial and sales milestones of clinical and commercial development and sales, certain of which milestones apply to development and sale of any Licensed Product as a monotherapy and certain of which milestones apply to development and sale of any Licensed Product in combination with another therapy modality for the treatment of solid tumors.

We are required to pay royalties to BWH upon first commercial sale of the Licensed Products, which are paid at an increasing rate as net sales increase, ranging from low single digits to high single digits. We also agreed to pay a single digit royalty rate on net sales of any products developed using certain BWH know-how but which is not covered by the licensed patent rights, or derived products.

We may reduce our royalty obligations to BWH on any product (but not derived products) by an agreed upon percentage if we are required to pay a royalty to a third party to avoid patent infringement claims in respect of our development and commercialization of Licensed Products. The royalty rate paid to BWH may not fall below a pre-specified percentage for the sale of any product and another percentage for the sale of any derived product.

Our obligation to pay royalties to BWH expires on a country-by-country basis on the latest of (i) the date upon which there ceases to be a valid claim of patent rights as further detailed in the BWH License Agreement in such country, (ii) expiration of statutory or regulatory exclusivity in such country and (iii) 10 years after the first commercial sale.

The BWH License Agreement also requires us to pay a percentage of any non-royalty income attributable to the sublicense, including (i) 2nd decile rates if such sublicense occurs prior to dosing the first patient in a Phase 2 trial, (ii) 1st decile rates if such sublicense occurs after dosing the first patient in a Phase 2 trial but before approval of a BLA by the FDA (or the equivalent approval and regulatory body in another major market country) and (iii) single digit rates if such sublicense occurs after approval of a BLA by the FDA (or the equivalent approval and regulatory body in another major market country).

The BWH License Agreement expires on the latest of (i) the 10th anniversary of the first commercial sale in the last country which has a commercial sale, (ii) the date on which all relevant issued patents and filed patent applications have expired or been abandoned and (iii) upon the expiration of market exclusivity on the applicable product.

The BWH License Agreement may be terminated by BWH (i) if we fail to pay any amounts owed under the terms of the agreement within a specified cure period, (ii) if we fail to maintain insurance in accordance with the BWH License Agreement, (iii) if we file for bankruptcy, or (iv) if we remain in default of the BWH License Agreement for non-financial reasons following a specified cure period to remedy the breach. The BWH License Agreement may be terminated by us for convenience upon 90 days' prior written notice.

Ventagen. On March 1, 2014, we entered into an exclusive license agreement, or the Ventagen Agreement, with Ventagen, LLC, or Ventagen. The Ventagen Agreement provides Ventagen an exclusive license, with rights to grant sublicenses (subject to certain terms and conditions) under any worldwide patent rights and know-how owned or controlled by us during the term of the Ventagen Agreement which cover applicable technology utilizing the delivery method of the herpes derived TK protein to tumors or other tissues via a viral vector (as further specified therein), to research, use, have used, import, have imported, export, have exported, offer for sale, have sold, sell, distribute and market certain products for the prevention or treatment of cancer in humans and any use in animals (or the Field of Use), or the Licensed Products, for commercial sale and distribution within Mexico, Belize, Guatemala, Honduras, El Salvador, Costa Rica, Nicaragua, Panama, Colombia and Bolivia (or the Territory).

Under the Ventagen Agreement, Ventagen agreed to use commercially reasonable efforts to develop and commercialize Licensed Products in the Territory in the Field of Use.

Ventagen agreed to pay us $1,000,000 for research and development, which we received in 2014 and 2015, and agreed to pay us a fixed future milestone payment of $2,500,000 upon Ventagen's achievement of a specified amount of sales of a Licensed Product, which is subject to certain reductions for our direct cost over a specified threshold.

Ventagen also agreed to purchase all of its clinical and commercial supply of Licensed Products from us required for clinical or commercial purposes at a price of cost plus a specified increase of the wholesale price of the Licensed Products, subject to a minimum and maximum price, through the end of the Royalty Term, which is defined as the period commencing on the effective date of the Ventagen Agreement and ending on a country-by-country basis on the later of (i) the last expiration date of the patent rights covering a Licensed Product, (ii) twelve years from the receipt of marketing authorization of the Licensed Product in the applicable country, or (iii) the date a generic version of a Licensed Product that is manufactured, owned or controlled by a third party is granted a market authorization. If we are unable or unwilling to manufacture supply under the terms of the Ventagen Agreement, Ventagen has the right to manufacture its own supply and will be required to pay to us a fixed fee per dose sold by Ventagen, its affiliates, agents, sublicensee or end users. We have also agreed to provide certain services to Ventagen related to Ventagen's development plan.

The Ventagen Agreement expires on the date of the expiration of the final Royalty Term in all countries in the Territory. The Ventagen Agreement may be terminated (i) by Ventagen at will upon 30 days' prior written notice to us, (ii) by us subject to a specified notice period if Ventagen files for bankruptcy or becomes insolvent or (iii) by us if Ventagen remains in material breach of the Ventagen Agreement following notice and a cure period to remedy the breach. Ventagen retains an irrevocable, perpetual, paid up, royalty-free license, with rights of sublicense to use, have used, lease, import and export, offer to sell, sell, have sold, product, distribute and market Licensed Products in each country in the Territory after the expiration of the Royalty Term in such country.

Certain of our current shareholders own 49.5% of the voting stock of Ventagen, but we do not hold any management position or run the day-to-day operations of Ventagen. See "Certain Relationships and Related Person Transactions."

Competition

The development and commercialization of new product candidates is highly competitive. We face competition from major pharmaceutical, specialty pharmaceutical and biotechnology companies among others with respect to CAN-2409 and CAN-3110 and will face similar competition with respect to any product candidates that we may seek to develop or commercialize in the future. We compete in pharmaceutical, biotechnology and other related markets that develop immune-oncology therapies for the treatment of cancer. There are other companies working to develop viral immunotherapies for the treatment of cancer including divisions of large pharmaceutical and biotechnology companies of various sizes. The large pharmaceutical and biotechnology companies that have commercialized and/or are developing immuno-oncology treatments for cancer include AstraZeneca, Bristol-Myers Squibb, Gilead Sciences, Inc., Merck & Co., Novartis, Pfizer and Genentech, Inc.

Some of the products and therapies developed by our competitors are based on scientific approaches that are the same as or similar to our approach, including with respect to the use of viral immunotherapy with adenovirus and

HSV. Other competitive products and therapies are based on entirely different approaches. We are aware that Oncorus, Inc., Replimune Group, Inc., Amgen Inc., ImmVira Co., Ltd., IconOVir Bio, Inc., and FerGene, Inc., among others, are developing viral immunotherapies that may have utility for the treatment of indications that we are targeting. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Many of the companies we compete against or may compete against in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in concentration of even more resources among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, in establishing clinical trial sites and enrolling subjects for our clinical trials and in acquiring technologies complementary to, or necessary for, our programs.

We could see a reduction or elimination of our commercial opportunity if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, or are more convenient or are less expensive than any products that we or our collaborators may develop. Our competitors also may obtain FDA or foreign regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of all our product candidates, if approved, are likely to be their efficacy, safety, convenience and price, if required, the level of biosimilar or generic competition and the availability of reimbursement from government and other third-party payors.

Commercialization

We intend to retain significant development and commercial rights to our product candidates and, if marketing approval is obtained, to commercialize our product candidates on our own, or potentially with a partner, in the United States and other regions. We currently have no sales, marketing or commercial product distribution capabilities and have no experience as a company commercializing products. We intend to build the necessary infrastructure and capabilities over time for the United States, and potentially other regions, following further advancement of our product candidates. Clinical data, the size of the addressable patient population, the size of the commercial infrastructure and manufacturing needs may all influence or alter our commercialization plans.

Manufacturing

We have established an operations leadership team with extensive experience in manufacturing biologics based on viruses, including oncolytic products and gene therapy products, and in the construction, validation, approval and operation of facilities designed to manufacture biologics.

Our team has developed a reproducible manufacturing process for our product candidates, and we are evaluating the development of a commercial-scale biologics manufacturing facility at our new headquarters in Needham, Massachusetts as well as using third-party contract manufacturing organizations for commercial scale manufacturing of our product candidates.

IP

We have obtained Orphan Drug Designation for CAN-2409 for the treatment of glioblastoma, which makes the product candidate eligible for a period of orphan drug exclusivity, if approved in this indication, under certain conditions.

We believe that approval of our CAN-2409 and CAN-3110 product candidates under a BLA will result in 12 years of data exclusivity in the United States under the ACA, 10 years of market exclusivity in Europe and significant durations in other markets, which would be complementary to any relevant patent exclusivity.

Through licensing and developing our own portfolio, we have rights to one issued composition of matter patent in the United States that relates to CAN-3110, which expires in 2036 and is exclusively licensed to us. We also own a

patent issued in the United States that relates to a method of use of CAN-2409 in combination with other agents that expires in 2034. There are also multiple patent applications in the United States and foreign countries, that are fully or partially owned by us or are exclusively licensed to us by the inventor owners.

Government Regulation

In the United States, biological products are subject to regulation under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and licensure under the Public Health Service Act (PHS Act), and other federal, state, local and foreign statutes and regulations. The FD&C Act and corresponding regulations govern, among other things, the research, development, clinical trial, testing, manufacturing, quality control, approval, safety, efficacy, labeling, packaging, storage, record keeping, distribution, reporting, marketing, promotion, export and import, advertising, post-approval monitoring, and post-approval reporting involving biological products. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources and we may not be able to obtain the required regulatory approvals.

Further, even if we obtain the required regulatory approvals for our products, pharmaceutical companies are subject to myriad federal, state, and foreign healthcare laws, rules, and regulations governing all aspects of our operations, including, but not limited to, our relationships with healthcare professionals, healthcare institutions, distributors of our products, and sales and marketing personnel; governmental and other third-party payor coverage and reimbursement of our products; and data privacy and security. Such laws, rules, and regulations are complex, continuously evolving, and, in many cases, have not been subject to extensive interpretation by applicable regulatory agencies or the courts. We are required to invest significant time and financial resources in policies, procedures, processes, and systems to ensure compliance with these laws, rules, and regulations, and our failure to do so may result in the imposition of substantial monetary or other penalties by federal or state regulatory agencies, give rise to reputational harm, or otherwise have a material adverse effect on our results of operations and financial condition.

U.S. biological products development process

The process required by the FDA before a biological product candidate may be licensed for marketing in the U.S. generally involves the following:

- completion of nonclinical laboratory tests and animal studies performed in accordance with FDA's good laboratory practices, or GLPs, requirements and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an application for an investigational new drug application, or IND, which must become effective before human clinical trials may begin;
- approval of the protocol and related documentation by an IRB or ethics committee at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials according to GCPs, requirements and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product candidate for its intended use;
- preparation of and submission to the FDA of a BLA for marketing approval that includes sufficient evidence of establishing the safety, purity, and potency of the proposed biological product for its intended indication, including from results of nonclinical testing and clinical trials;
- a determination by the FDA within 60 days of its receipt of a BLA to accept and file the application;
- satisfactory completion of an FDA pre-license inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with current good manufacturing practices, or cGMPs, to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity;
- satisfactory completion of an FDA advisory committee review, if applicable;
- potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA in accordance with any applicable expedited programs or designations;
- payment of user fees for FDA review of the BLA (unless a fee waiver applies); and
- FDA review and approval, or licensure, of the BLA to permit commercial marketing of the product for particular indications for use in the U.S.

Pre-clinical Studies and the IND Process

Before testing any biological product candidate in humans, the product candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of the product's biological characteristics, chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs.

Prior to commencing an initial clinical trial in humans with a product candidate in the U.S., an IND must be submitted to the FDA and the FDA must allow the IND to proceed. An IND is an exemption from the FD&C Act that allows an unapproved product candidate to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA allowance that such investigational product may be administered to humans in connection with such trial. Such authorization must be secured prior to interstate shipment and administration. In support of a request for an IND, the clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND must become effective before human clinical trials may begin. Once submitted, the IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the IND on a full or partial clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial or part of the study can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial. The FDA also may impose clinical holds on a sponsor's IND at any time before or during clinical trials due to, among other considerations, unreasonable or significant safety concerns, inability to assess safety concerns, lack of qualified investigators, a misleading or materially incomplete investigator brochure, study design deficiencies, interference with the conduct or completion of a study designed to be adequate and well-controlled for the same or another investigational product, insufficient quantities of investigational product, lack of effectiveness, or non-compliance. If the FDA imposes a clinical hold, studies may not recommence without FDA authorization and then only under terms authorized by the FDA.

Clinical Trials

Clinical trials involve the administration of the biological product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under control of the trial sponsor. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters and criteria to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all research subjects provide informed consent. An IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the trial at least annually. The IRB must review and approve, among other things, the trial protocol and informed consent information to be provided to trial subjects. An IRB must operate in compliance with FDA regulations. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

Some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board or committee, or DSMB. This group provides authorization as to whether or not a trial may move forward at designated check points based on access that only the group maintains to available data from the trial and may recommend halting the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy.

Certain information about certain clinical trials must also be submitted within specific timeframes to the NIH for public dissemination on its ClinicalTrials.gov website.

Clinical trials typically are conducted in three sequential phases that may overlap or be combined:

- Phase 1. The biological product candidate is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may

be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the biological product candidate in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.

- Phase 2. The biological product candidate is evaluated in a limited patient population with a specific disease or condition to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3. The biological product candidate is administered to an expanded patient population to further evaluate dosage, clinical efficacy, potency, and safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product candidate and provide an adequate basis for approval and product labeling.

In August 2018, the FDA released a draft guidance entitled “Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics,” which outlines how developers can utilize an adaptive trial design commonly referred to as a seamless trial design in early stages of oncology biological product development (i.e., the first-in-human clinical trial) to compress the traditional three phases of trials into one continuous trial called an expansion cohort trial. Information to support the design of individual expansion cohorts are included in IND applications and assessed by FDA. Expansion cohort trials can potentially bring efficiency to biological product development and reduce developmental costs and time.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may also be made a condition to approval of the BLA. Failure to exhibit due diligence with regard to conducting required Phase 4 clinical trials could result in withdrawal of approval for products.

Concurrent with clinical trials, companies usually complete additional animal studies and also must develop additional information about the chemistry and physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the Public Health Service Act, or PHS Act, emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

Both the FDA and the EMA provide expedited pathways for the development of biological product candidates for treatment of rare diseases, particularly life threatening diseases with high unmet medical need. Such biological product candidates may be eligible to proceed to registration following a single clinical trial in a limited patient population, sometimes referred to as a Phase 1/2 trial, but which may be deemed a pivotal or registrational trial following review of the trial’s design and primary endpoints by the applicable regulatory agencies. Determination of the requirements to be deemed a pivotal or registrational trial is subject to the applicable regulatory authority’s scientific judgement and these requirements may differ in the U.S. and the European Union.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or *in vitro* testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor’s initial receipt of the information.

Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some trials also include oversight by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board, which provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy.

U.S. review and approval processes

Assuming successful the completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include results of product development, laboratory and animal studies, human clinical trials, information on the manufacture and composition of the product, proposed labeling and other relevant information. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the FDA accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review to determine if it is substantially complete before the FDA accepts it for filing. In most cases, the submission of a BLA is subject to a substantial application user fee, although the fee may be waived under certain circumstances. Under the performance goals and policies implemented by the FDA under the Prescription Drug User Fee Act, or PDUFA, for original BLAs, the FDA targets ten months from the filing date in which to complete its initial review of a standard application and respond to the applicant, and six months from the filing date for an application with priority review. The FDA does not always meet its PDUFA goal dates, and the review process is often significantly extended by FDA requests for additional information or clarification. This review typically takes twelve months from the date the BLA is submitted to the FDA because the FDA has approximately two months to make a “filing” decision. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the BLA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, pure and potent for its intended use and whether the product is being manufactured in accordance with cGMP to ensure its continued safety, purity and purity. The FDA may refer applications for novel biological products or biological products that present difficult or novel questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the biological product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS; the FDA will not approve the BLA without a REMS, if required.

Before approving a BLA, the FDA typically will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements. To assure cGMP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production and quality control.

Under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA for a novel product (e.g., new active ingredient, new indication, etc.) must contain data to assess the safety and effectiveness of the biological

product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, including to subpopulations of patients, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings, precautions or interactions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a REMS, or otherwise limit the scope of any approval. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing trials. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could impact the timeline for regulatory approval or otherwise impact ongoing development programs.

Orphan product designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S., or 200,000 or more individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making a biological product available in the U.S. for this type of disease or condition will be recovered from sales of the product. Orphan product designation must be requested before submitting a BLA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

Orphan product designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. If a product that has orphan product designation subsequently receives the first FDA approval for a particular active ingredient for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan product exclusivity. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan product exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same biological product as defined by the FDA or if a product candidate is determined to be contained within the competitor's product for the same indication or disease. If a biological product designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity. In addition, orphan drug exclusive marketing rights in the U.S. may be lost if the FDA later determines that the request for designation was materially defective or, as

noted above, if the second applicant demonstrates that its product is clinically superior to the approved product with orphan exclusivity or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Orphan drug status in the European Union has similar, but not identical, benefits.

Expedited development and review programs

The FDA has various programs, including fast track designation, breakthrough therapy designation, accelerated approval and priority review, that are intended to expedite or simplify the process for the development and FDA review of drugs and biologics that are intended for the treatment of serious or life-threatening diseases or conditions. To be eligible for fast track designation, new drugs and biological product candidates must be intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biologic may request the FDA to designate the drug or biologic as a fast track product at any time during the clinical development of the product. One benefit of fast track designation, for example, is that the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted if certain conditions are satisfied, including an agreement with the FDA on the proposed schedule for submission of portions of the application and the payment of applicable user fees before the FDA may initiate a review.

Under the FDA's breakthrough therapy program, a sponsor may seek FDA designation of its product candidate as a breakthrough therapy if the product candidate is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that it may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough therapy designation comes with all of the benefits of fast track designation. The FDA may take other actions appropriate to expedite the development and review of the product candidate, including holding meetings with the sponsor and providing timely advice to, and interactive communication with, the sponsor regarding the development program.

A product candidate is eligible for priority review if it treats a serious or life-threatening disease or condition and, if approved, would provide a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious disease or condition. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biological product designated for priority review in an effort to facilitate the review. Under priority review, the FDA's goal is to review an application in six months once it is filed, compared to ten months for a standard review. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Additionally, a product candidate may be eligible for accelerated approval. Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on an intermediate clinical endpoint other than survival or irreversible morbidity or mortality, that is reasonably likely to predict irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA generally requires that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials to verify the clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. The FDA may withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product.

Post-approval requirements

Rigorous and extensive FDA regulation of biological products continues after approval, particularly with respect to cGMP requirements, as well as requirements relating to record keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. Manufacturers of

products are required to comply with applicable requirements in the cGMP regulations, including quality control and quality assurance and maintenance of records and documentation. Other post-approval requirements applicable to biological products, include reporting of cGMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record keeping requirements, reporting of adverse effects, reporting updated safety and efficacy information, and complying with electronic record and signature requirements. After a BLA is approved, the product also may be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products.

Manufacturers must comply with the FDA's advertising and promotion requirements, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet. Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical holds, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, product detentions or refusal to permit the import or export of the product, restrictions on the marketing or manufacturing of the product, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors or other stakeholders, debarment, restitution, disgorgement of profits, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Biological product manufacturers and other entities involved in the manufacture and distribution of approved biological products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including withdrawal of the product from the market. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

U.S. patent term restoration and marketing exclusivity

Depending upon the timing, duration and specifics of the FDA approval of a biological product, some of a sponsor's U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved biological product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. In addition, a patent can only be extended once and only for a single product. The U.S. PTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may intend to apply for restoration of patent term for one of our patents, if and as applicable, to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

A biological product can obtain pediatric market exclusivity in the U.S. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods, including some regulatory exclusivity periods tied to patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed reference biological product. This amendment to the PHS Act attempts to minimize duplicative testing. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical trial or trials. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structure of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation that are still being worked out by the FDA.

FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product, and FDA will not approve an application for a biosimilar or interchangeable product based on the reference biological product until 12 years after the date of first licensure of the reference product. "First licensure" typically means the initial date the particular product at issue was licensed in the U.S. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity, or potency. The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate implementation and impact of the BPCIA is subject to significant uncertainty.

U.S. regulation of companion diagnostics

Our product candidates may require use of an *in vitro* diagnostic to identify appropriate patient populations. These diagnostics, often referred to as companion diagnostics, are regulated as medical devices. In the U.S., the FD&C Act and its implementing regulations and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import and post-market surveillance. Unless an exemption applies, companion diagnostic tests require marketing clearance or approval from the FDA prior to commercial distribution. The two primary types of FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, and premarket approval, or PMA approval.

If use of companion diagnostic is essential to safe and effective use of a drug or biologic product, then the FDA generally will require approval or clearance of the diagnostic contemporaneously with the approval of the therapeutic product. On August 6, 2014, the FDA issued a final guidance document addressing the development and approval process for "*In Vitro* Companion Diagnostic Devices." According to the guidance, for novel candidates such as our product candidates, a companion diagnostic device and its corresponding drug or biologic candidate should be approved or cleared contemporaneously by FDA for the use indicated in the therapeutic product labeling. The guidance also explains that a companion diagnostic device used to make treatment decisions in clinical trials of a biologic product candidate generally will be considered an investigational device, unless it is employed for an

intended use for which the device is already approved or cleared. If used to make critical treatment decisions, such as patient selection, the diagnostic device generally will be considered a significant risk device under the FDA's Investigational Device Exemption, or IDE, regulations. Thus, the sponsor of the diagnostic device will be required to comply with the IDE regulations. According to the guidance, if a diagnostic device and a drug are to be studied together to support their respective approvals, both products can be studied in the same investigational study, if the study meets both the requirements of the IDE regulations and the IND regulations. The guidance provides that depending on the details of the study plan and subjects, a sponsor may seek to submit an IND alone, or both an IND and an IDE. In July 2016, the FDA issued a draft guidance document intended to further assist sponsors of therapeutic products and sponsors of *in vitro* companion diagnostic devices on issues related to co-development of these products.

The FDA generally requires companion diagnostics intended to select the patients who will respond to cancer treatment to obtain approval of a PMA for that diagnostic contemporaneously with approval of the therapeutic. The review of these *in vitro* companion diagnostics in conjunction with the review of therapeutic candidates such as those we are developing involves coordination of review by the FDA's Center for Biologics Evaluation and Research and by the FDA's Center for Devices and Radiological Health. The PMA process, including the gathering of clinical and pre-clinical data and the submission to and review by the FDA, can take several years or longer. It involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications are also subject to an application fee.

PMAs for certain devices must generally include the results from extensive pre-clinical and adequate and well-controlled clinical trials to establish the safety and effectiveness of the device for each indication for which FDA approval is sought. In particular, for a diagnostic, the applicant must demonstrate that the diagnostic produces reproducible results when the same sample is tested multiple times by multiple users at multiple laboratories. In addition, as part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with the Quality System Regulation, or QSR, which imposes elaborate testing, control, documentation and other quality assurance requirements.

If the FDA evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or a not-approvable letter, which usually contains a number of conditions that must be met in order to secure the final approval of the PMA, such as changes in labeling, or specific additional information, such as submission of final labeling, in order to secure final approval of the PMA. If the FDA concludes that the applicable criteria have been met, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the applicant. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution.

If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will issue an order denying approval of the PMA or issue a not approvable order. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the PMA. Once granted, PMA approval may be withdrawn by the FDA if compliance with post approval requirements, conditions of approval or other regulatory standards is not maintained or problems are identified following initial marketing. PMA approval is not guaranteed, and the FDA may ultimately respond to a PMA submission with a not approvable determination based on deficiencies in the application and require additional clinical trial or other data that may be expensive and time-consuming to generate and that can substantially delay approval.

After a device is placed on the market, it remains subject to significant regulatory requirements. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. Device manufacturers must also establish registration and device listings with the FDA. A medical device manufacturer's manufacturing processes and those of its suppliers are required to comply with the applicable portions of the QSR, which cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. Domestic facility records and manufacturing processes are subject to

periodic unscheduled inspections by the FDA. The FDA also may inspect foreign facilities that export products to the U.S.

Additional regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines.

Government regulation outside of the United States

In addition to regulations in the U.S., we are subject to a variety of regulations in other jurisdictions governing, among other things, research and development, clinical trials, testing, manufacturing, safety, efficacy, labeling, packaging, storage, record keeping, distribution, reporting, advertising and other promotional practices involving biological products as well as authorization and approval of our products. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension of clinical trials, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Clinical trials regulation

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the U.S. have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the European Union, for example, a CTA must be submitted for each clinical trial to each country's national competent authority, or NCA, and at least one independent ethics committee, or EC, much like the FDA and an IRB, respectively. Once the CTA is approved in accordance with a country's requirements, the corresponding clinical trial may proceed. Under the current regime (the EU Clinical Trials Directive 2001/20/EC and corresponding national laws) all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the EU Member State where they occurred.

In April 2014, the EU adopted a new Clinical Trials Regulation (EU) No 536/2014, which is set to replace the current Clinical Trials Directive 2001/20/EC. It will overhaul the current system of approvals for clinical trials in the EU. Specifically, the new Regulation, which will be directly applicable in all Member States (meaning that no national implementing legislation in each EU Member State is required), aims at simplifying and streamlining the approval of clinical trials in the EU. For instance, the new Regulation provides for a streamlined application procedure via a single entry point and strictly defined deadlines for the assessment of clinical trial applications. It is expected that the new Regulation will come into effect following confirmation of full functionality of the Clinical Trials Information System, the centralized EU portal and database for clinical trials foreseen by the new Regulation, through an independent audit, which is currently expected to occur in December 2021.

European Union drug review and approval

In the European Economic Area, or EEA, medicinal products can only be commercialized after obtaining a marketing authorization. To obtain regulatory approval of a medicinal product in the EEA, we must submit a marketing authorization application, or MAA. A centralized marketing authorization is issued by the European Commission through the centralized procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the EMA, and is valid throughout the EEA. The centralized procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicinal products such as (gene-therapy, somatic cell-therapy or tissue-engineered medicines), and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders,

diabetes, auto-immune and other immune dysfunctions, and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EEA.

Under the centralized procedure the maximum timeframe for the evaluation of a MAA by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. Clock stops may extend the timeframe of evaluation of a MAA considerably beyond 210 days. Where the CHMP gives a positive opinion, it provides the opinion together with supporting documentation to the European Commission, who make the final decision to grant a marketing authorization, which is issued within 67 days of receipt of the EMA's recommendation. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of a MAA under the accelerated assessment procedure is 150 days, excluding clock stops, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that the application is no longer appropriate to conduct an accelerated assessment.

The application used to submit the BLA in the U.S. is similar to that required in the European Union, although there may be certain specific requirements, for example those set out in Regulation (EC) No 1394/2007 on Advanced Therapy Medicinal Products, covering gene therapy, somatic cell therapy and tissue-engineered medicinal products.

Now that the UK (which comprises Great Britain and Northern Ireland) has left the European Union, Great Britain will no longer be covered by centralized marketing authorizations (under the Northern Irish Protocol, centralized marketing authorizations will continue to be recognized in Northern Ireland). All medicinal products with a current centralized marketing authorization were automatically converted to Great Britain marketing authorizations on January, 1 2021. For a period of two years from January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or MHRA, the UK medicines regulator, may rely on a decision taken by the European Commission on the approval of a new marketing authorization in the centralized procedure, in order to more quickly grant a new Great Britain marketing authorization. A separate application will, however, still be required.

Data and market exclusivity

In the EEA, upon receiving marketing authorization, innovative medicinal products generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents generic or biosimilar applicants from referencing the innovator's pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the EEA, during a period of eight years from the date on which the reference product was first authorized in the EEA. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization application can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be marketed until the expiration of the market exclusivity. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to authorization, is held to bring a significant clinical benefit in comparison with existing therapies. There is no guarantee that a product will be considered by the EMA to be an innovative medicinal product, and products may not qualify for data exclusivity. Even if a product is considered to be an innovative medicinal product so that the innovator gains the prescribed period of data exclusivity, another company may market another version of the product if such company obtained a marketing authorization based on a MAA with a completely independent data package of pharmaceutical tests, preclinical tests and clinical trials.

Orphan drug designation and exclusivity

Products receiving orphan designation in the EEA can receive ten years of market exclusivity, during which time no "similar medicinal product" may be placed on the market. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. An orphan product can also obtain an additional two years of market exclusivity in the European Union where an agreed Pediatric Investigation Plan for pediatric studies has been complied with. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications.

The criteria for designating an “orphan medicinal product” in the EEA are similar in principle to those in the U.S. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as orphan if it meets the following criteria: (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five (5) in ten thousand (10,000) persons in the EEA when the application is made, or (b) it is unlikely that the product, without the benefits derived from orphan status, would generate sufficient return in the European Union to justify the necessary investment in its development; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EEA, or if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication. The application for orphan drug designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the MAA if the orphan drug designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The 10-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar medicinal product for the same indication at any time if:

- the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;
- the marketing authorization holder of the authorized product consents to a second orphan medicinal product application; or
- the marketing authorization holder of the authorized product cannot supply enough orphan medicinal product.

Pediatric development

In the EEA, companies developing a new medicinal product must agree upon a Pediatric Investigation Plan, or PIP, with the EMA’s pediatric committee, or PDCO, and must conduct pediatric clinical trials in accordance with that PIP, unless a waiver applies (e.g., because the relevant disease or condition occurs only in adults). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which marketing authorization is being sought. The marketing authorization application for the product must include the results of pediatric clinical trials conducted in accordance with the PIP, unless a waiver applies, or a deferral has been granted by the PDCO of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults, in which case the pediatric clinical trials must be completed at a later date. Products that are granted a marketing authorization with the results of the pediatric clinical trials conducted in accordance with the PIP are eligible for a six month extension of the protection under a supplementary protection certificate (if any is in effect at the time of approval) even where the trial results are negative. In the case of orphan medicinal products, a two year extension of the orphan market exclusivity may be available. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

Post-approval controls

Following approval, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of the medicinal product. These include the following:

- The holder of a marketing authorization must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance, who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.
- All new MAAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with

the product. The regulatory authorities may also impose specific obligations as a condition of the marketing authorization. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies. RMPs and PSURs are routinely available to third parties requesting access, subject to limited redactions.

- All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, or SmPC, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the European Union. Although general requirements for advertising and promotion of medicinal products are established under European Union directives, the details are governed by regulations in each European Union Member State and can differ from one country to another.

Brexit and the Regulatory Framework in the United Kingdom

In June 2016, the electorate in the UK voted in favor of leaving the European Union (commonly referred to as “Brexit”). Thereafter, in March 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The UK formally left the European Union on January 31, 2020. A transition period began on February 1, 2020, during which European Union pharmaceutical law remained applicable to the UK, however this ended on December 31, 2020. On December 24, 2020, the UK and European Union entered into a Trade and Cooperation Agreement. The agreement sets out certain procedures for approval and recognition of medical products in each jurisdiction. Since the regulatory framework in the UK covering the quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from EU Directives and Regulations, Brexit could materially impact the future regulatory regime which applies to products and the approval of product candidates in the UK, as the UK legislation now has the potential to diverge from EU legislation. It remains to be seen how Brexit will impact regulatory requirements for product candidates and products in the UK in the long-term. The MHRA has recently published detailed guidance for industry and organizations to follow from January 1, 2021 now the transition period is over, which will be updated as the UK’s regulatory position on medicinal products evolves over time.

Coverage and Reimbursement

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Thus, even if a product candidate is approved, sales of the product will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for, the product. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. No uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, which will require additional expenditure above and beyond the costs required to obtain FDA or other comparable regulatory approvals. Additionally, companies may also need to provide discounts to purchasers, private health plans or government healthcare programs. Nonetheless, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover a product could reduce physician utilization once the product is approved and have a material adverse effect on sales, our operations

and financial condition. Additionally, a third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of products have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Other Healthcare Laws and Compliance Requirements

Healthcare providers, physicians, and third-party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our business operations and any current or future arrangements with third-party payors, healthcare providers and physicians may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we develop, market, sell and distribute any drugs for which we obtain marketing approval. In the United States, these laws include, without limitation, state and federal anti-kickback, false claims, physician transparency, and patient data privacy and security laws and regulations, including but not limited to those described below.

- The federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity need not have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act.
- The federal civil and criminal false claims laws, including the civil False Claims Act, or FCA, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false, fictitious or fraudulent; knowingly making, using, or causing to be made or used, a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs.
- The federal civil monetary penalties laws impose civil fines for, among other things, the offering or transfer or remuneration to a Medicare or state healthcare program beneficiary, if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state health care program, unless an exception applies.

- The Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for knowingly and willfully executing a scheme, or attempting to execute a scheme, to defraud any healthcare benefit program, including private payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, or falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity may be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, impose, among other things, specified requirements on covered entities and their respective business associates relating to the privacy and security of individually identifiable health information including mandatory contractual terms and required implementation of technical safeguards of such information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates in some cases, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.
- The Physician Payments Sunshine Act, enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, imposed new annual reporting requirements for certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, for certain payments and "transfers of value" provided to physicians (currently defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made in the previous year to certain non-physician providers such as physician assistants and nurse practitioners.
- Federal consumer protection and unfair competition laws broadly regulate marketplace activities and activities that potentially harm consumers.
- Analogous state and foreign laws and regulations, including, but not limited to, state anti-kickback and false claims laws, may be broader in scope than the provisions described above and may apply regardless of payor. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and relevant federal government compliance guidance; require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers; restrict marketing practices or require disclosure of marketing expenditures and pricing information. State and foreign laws may govern the privacy and security of health information in some circumstances. These data privacy and security laws may differ from each other in significant ways and often are not pre-empted by HIPAA, which may complicate compliance efforts.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other related governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, disgorgement, exclusion from government funded healthcare programs, such as Medicare and Medicaid, reputational harm, additional oversight and reporting obligations if we become subject to a corporate integrity agreement or similar settlement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to similar actions, penalties and sanctions. Ensuring business arrangements

comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from its business.

Employees and Human Capital Resources

As of June 25, 2021, we had 50 employees. Of these employees, 36 perform research and development functions. None of our employees are represented by a labor union and we believe we maintain good relations with our employees.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Legal proceedings

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are probable to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources and other factors.

MANAGEMENT

Executive Officers and Directors

The following table sets forth certain information about our executive officers, significant employees and directors, including their ages as of June 21, 2021.

NAME	AGE	POSITION(S)
Executive Officers:		
Paul Peter Tak, M.D., Ph.D., FMedSci	61	President and Chief Executive Officer, Director
Estuardo Aguilar-Cordova, M.D., Ph.D.(3)	63	Founder and Chief Scientific Officer, Director
Laura K. Aguilar, M.D., Ph.D.	56	Chief Medical Officer
Nathan Caffo	52	Chief Business Officer
John Canepa	65	Chief Financial Officer
Susan Stewart, J.D.	60	Chief Regulatory Officer
Non-Employee Directors:		
Carrie S. Cox	63	Chairman
Edward J. Benz, Jr., M.D.(3)	75	Director
Paul B. Manning(2)	65	Director
Chris Martell(1)(2)	42	Director
Udi Meirav, Ph.D.(1)	60	Director
Diem Nguyen, Ph.D.	49	Director
Alan E. Smith, Ph.D., FRS, CBE(2)	75	Director
Shaan C. Gandhi, M.D., D.Phil.(1)(3)	35	Director
Key Employees:		
Francesca Barone	44	Vice President, Head of Research
Chris Matheny	49	Vice President, Development Leader

(1) Member of the Audit Committee.

(2) Member of the Compensation Committee.

(3) Member of the Nominating and Corporate Governance Committee.

Executive Officers

Paul Peter Tak, M.D., Ph.D., FMedSci, has served as President and Chief Executive Officer of Candel since September 2020. He received his medical degree cum laude from the Free University in Amsterdam and was trained as an internist, rheumatologist and immunologist at Leiden University Medical Center, where he also received his Ph.D. He has been Clinical Associate Professor of Medicine at the University of California San Diego. Next, he served as Professor of Medicine and founding Chair of the Department of Clinical Immunology and Rheumatology at the Academic Medical Centre/University of Amsterdam (AMC). During this time, he founded Arthrogen b.v., a biotech company focused on gene therapy. He has published extensively in peer-reviewed journals and received numerous awards. He has been elected Fellow of the Academy of Medical Sciences (U.K.). At GlaxoSmithKline he served as Senior Vice President, Chief Immunology Officer, and Global Development Leader from 2011 to 2018. He oversaw the creation of a portfolio of new medicines for immune-mediated inflammatory diseases, cancer, infectious disease and pain, including anti-OSM antibody, anti-LAG3 antibody, ESM-BET inhibitor, RIP1 kinase inhibitor, anti-GM-CSF antibody, anti-CCL17 antibody, Benlysta sc, gepotidacin, molibresib (BET inhibitor), belantamab mafodotin (anti-BCMA antibody-drug conjugate), and NY-ESO1 SPEAR T cell therapy. He was the Chair of the Scientific Review Board, the governing body accountable for the scientific assessment of GSK's R&D portfolio. From 2018 to 2020, Dr. Tak served as venture partner at Flagship Pioneering and also as President and CEO of Kintai Therapeutics, a start-up focused on enteric signaling networks, where he oversaw the creation of a portfolio of proprietary small molecules called precision enteric medicines for the treatment of obesity, neurological disease, and cancer. In addition, he has served as President and CEO of Tempero Pharmaceuticals, Board Member of Galvani Bioelectronics, ViiV Healthcare, Sitryx Therapeutics (co-founder), Omega Therapeutics, Levicept, and Citryll.

Estuardo Aguilar-Cordova, M.D., Ph.D., has served as our Founder and Chief Scientific Officer since September 2020 and previously served as our Chief Executive Officer from 2002 until September 2020. He has more than 30 years of

experience in the fields of biotherapeutics, cancer research and drug development, including serving as principal or co-investigator in more than 25 clinical trials ranging from Phase I to Phase III. Prior to starting Candel, Dr. Aguilar-Cordova held academic positions for nearly two decades. Most recently, he was deputy director of the Harvard Gene Therapy Initiative at Harvard Medical School in Boston and was a faculty member in Pediatrics, Hematology-Oncology at Baylor College of Medicine in Houston. He has served on numerous national oversight committees, including roles as chairman and member of the NIH Recombinant Advisory Committee (RAC), as a consultant to the FDA Biological Response Modifiers Advisory Committee (BRMAC), and as a member of the Vaccine and Related Products Advisory Committee (VRPAC). Dr. Aguilar-Cordova has also held other appointments including president of the Latin American Gene Therapy Society. Dr. Aguilar-Cordova has published more than 80 peer-reviewed scientific publications and book chapters, is on the editorial board of various professional journals and is an inventor on several patent applications. Dr. Aguilar-Cordova has an undergraduate degree in Biology and Chemistry from California State University, Bakersfield, an M.D. Inf. from the University del Valle de Guatemala and a Ph.D. from the University of California, Davis.

Laura K. Aguilar, M.D., Ph.D., has served as our Chief Medical Officer since 2014 and previously served as Vice President, Clinical Research from 2006 to 2014. In her role, Dr. Aguilar develops clinical trial strategies and oversees clinical trial activities to move the company forward in research and development. As chief clinical lead, she works with physicians, regulatory authorities and business partners, builds and maintains key opinion leader relationships, and advises clinical teams at study sites. Prior to joining Candel, Dr. Aguilar was an attending physician in Pediatric Oncology at Dana-Farber Cancer Institute and Children's Hospital in Boston, MA from 2001 to 2009. She also served as associate director and clinical liaison for the Harvard Gene Therapy Initiative. Dr. Aguilar has an undergraduate degree in Biochemistry from the University of California at Davis, and an M.D. and Ph.D. in Immunology from Baylor College of Medicine in Houston, TX. She completed her Pediatric residency and a Pediatric Hematology Oncology fellowship at Texas Children's Hospital in Houston.

Nathan Caffo, has been Candel's Chief Business Officer since September 2020. From September 2018 to September 2020, he was CBO at ALX Oncology, an immuno-oncology company, where he played a central role in the company's financing including series B and C and debt financings totaling $120 million, as well as the company's $186 million initial public offering. He was also responsible for all strategic partnering activities. Prior to ALX Oncology, from April 2009 to August 2018 he was President and CEO of Presage Biosciences, an oncology company that developed the first intratumoral microdosing platform for evaluation of multiple oncology agents. While at Presage he led the company's partnering strategy, resulting in over $30 million in upfront cash. Mr. Caffo's 26-year industry career has been focused on cancer therapeutics, personalized medicine, and applications of genomic technology. Mr. Caffo also led drug in-licensing at Perlegen Sciences, a genomic medicine spin-off of Affymetrix. Prior to that, he worked at Applied Biosystems (now Life Technologies) and its sister company Celera (now Quest Diagnostics) for 11 years in a number of technical and business roles, including managing the company's genomics service business. Mr. Caffo has a B.S. in Microbiology from Pennsylvania State University.

John Canepa, has been Candel's Chief Financial Officer since December 2020. Mr. Canepa has over 40 years of experience in the life science industry as an audit partner with a large international public accounting firm, and as a financial executive with public and private life science companies. Prior to joining Candel, he served as Senior Advisor, Acting CFO of Frequency Therapeutics from December 2018 until November 2020. During this time, Frequency completed several public and private financings, including its initial public offering in October 2019, and dramatically expanded its operations. Prior to joining Frequency, Mr. Canepa served as CFO of Agilis Biotherapeutics from December 2017 to August 2018 and was instrumental in its sale to PTC Therapeutics in August 2018. Prior to Agilis, he was COO and CFO of Asterand Bioscience from October 2012 to August 2017 and led its sale to a private equity group in 2017. Mr. Canepa began his career at Arthur Andersen & Co. and was with the firm for 23 years. He was a partner in the Boston office technology practice and the worldwide leader of the firm's life science practice. Mr. Canepa received a B.A. in Economics from Denison University and a Master's Degree in Finance from Michigan State University. John is a Trustee of Mount Auburn Hospital in Cambridge Massachusetts, where he currently serves as co-chair of the board of trustees and is on the board of the Beth Israel Lahey Health network.

Susan Stewart, J.D., has served as Candel's Chief Regulatory Officer since October 2020. Ms. Stewart has worked for more than 28 years in biopharmaceutical regulatory affairs, with significant experience devising innovative

strategies for novel therapeutics, overseeing regulatory submissions at various stages of product development and leading interactions with global health authorities. As an independent consultant, she also serves as Chief Regulatory Officer at Kaleido Biosciences, and had served as senior vice president of regulatory affairs and quality at Kaleido Biosciences, senior vice president of regulatory affairs, quality, and compliance at Tokai Pharmaceuticals and vice president, regulatory affairs at Transmolecular. She also spent 13 years at Genzyme Corporation in regulatory and compliance roles, including serving as vice president, regulatory affairs after beginning her career with Abbott Laboratories. She received her J.D. from Concord Law School at Purdue University Global, her LL.M. from the Maurice A. Deane School of Law at Hofstra University and her B.A. from the University of Massachusetts. She is a Fellow of the Regulatory Affairs Professionals Society (RAPS), a Director of the Board, and holds Regulatory Affairs Certifications (RAC) for both the U.S. and Europe.

Non-Employee Directors

Carrie S. Cox has served as a member of our board of directors since May 2021. She served as the Chairman and Chief Executive Officer of Humacyte, Inc., a regenerative medical technology company, from 2010 until June 2018, and served as its Executive Chairman from June 2018 to May 2019. Ms. Cox previously served as EVP and President, Global Pharmaceuticals, at Schering-Plough Corporation, from 2003 until its merger with Merck & Co., Inc., in November 2009. Prior to that, from 1997 to 2003, she held the role of President, Global Prescription Business at Pharmacia Corporation. Ms. Cox currently serves as a member of the Boards of Directors of Texas Instruments Inc. (Nasdaq: TXN) and Cardinal Health (NYSE: CAH), and she has served as Chairman of Selecta Biosciences (Nasdaq: SELB) since November 2019. She is currently Chairman of Organon & Co. (NYSE: OGN). Ms. Cox also served on the board of directors of Celgene Corp. from 2009 until its acquisition by Bristol-Myers Squibb Co. in November 2019, on the board of directors of electroCore, Inc. (Nasdaq: ECOR) between June 2018 and March 2020, and as Chairman of the board of directors of Array BioPharma, Inc. from August 2018 until its acquisition by Pfizer Inc. in July 2019. She received her B.S. from Massachusetts College of Pharmacy in 1981, and was a Registered Pharmacist. We believe that Ms. Cox's leadership in the biopharmaceutical industry, including both in operating roles and as a corporate director, provide her with the appropriate set of skills to serve as a member of our board of directors. Ms. Cox has notified us that she will resign from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part. Ms. Cox's resignation is due to her existing professional obligations and not due to any disagreement with us or any matters relating to our operations, policies or practices. Following her resignation from our board of directors, Ms. Cox will continue to serve as a Special Advisor to the CEO of Candel.

Edward J. Benz, Jr., M.D., has served as a member of our board of directors since September 2017. Dr. Benz is the President and CEO Emeritus of the Dana-Farber Cancer Institute and a member of the Dana-Farber Cancer Institute Board of Directors. Dr. Benz is an expert in blood disorders and is board certified in both hematology and internal medicine. He is an active clinical hematologist and a National Institutes of Health (NIH) funded researcher with a focus on the molecular basis and genetics around inherited blood disorders. From October 2000 until his retirement in October 2016, Dr. Benz served as President and CEO of Dana-Faber Cancer Institute and the Richard and Susan Smith Professor of Medicine and Professor of Genetics at Harvard Medical School. Prior to his role at Dana-Farber, Dr. Benz served as chairman for the Department of Medicine and Sir William Osler Professor of Medicine at Johns Hopkins University School of Medicine, as well as physician in chief at Johns Hopkins Hospital. Dr. Benz has also served as President of the American Society of Hematology, the Association of American Cancer Institutes, the American Society for Clinical Investigation, the American Clinical and Climatological Society, and the Friends of the National Institute of Nursing Research. Over the course of his career, Dr. Benz has authored more than 300 articles, books, reviews and abstracts and has received numerous awards. Dr. Benz serves on the board of directors of F-star Therapeutics, Inc. (NASDAQ: FSTX) and Deciphera Pharmaceuticals, Inc. (NASDAQ: DCPH), and also serves on the board of directors of Renovacor, Inc. and serves on our Research Advisory Board. We believe Dr. Benz's experience in the field of hematology and blood disorders provides him with the appropriate set of skills to serve as a member of our board of directors.

Paul B. Manning has served as a member of our board of directors since November 2018. Mr. Manning currently serves as the Chief Executive Officer of PBM Capital Group, LLC, or PBM Capital, a private equity investment firm in the business of investing in healthcare and life-science related companies, which he founded in 2010. Mr. Manning is a member of the board of directors of Liquidia Corporation (NASDAQ: LQDA) and Taysha Gene Therapies, Inc. (NASDAQ: TSHA), and he currently serves as Chairman of the board of directors of Verrica Pharmaceuticals Inc. (NASDAQ: VRCA) He previously served on the board of directors of Dova Pharmaceuticals, Inc., a biopharmaceutical company, from September 2016 to November 2019, and AveXis, Inc., a gene therapy company, from April 2014 to

May 2018. Mr. Manning received a B.S. in microbiology from the University of Massachusetts. We believe Mr. Manning's 30 years of managerial and operational experience in the healthcare industry and as an investor in healthcare related companies provides him with the appropriate set of skills to serve as a member of our board of directors.

Chris Martell has served as a member of our board of directors since November 2018. Chris Martell is the manager of GTAM1 2012 ADV LLC and an investor at Martell Capital. Previously, Chris was a Partner at PBM Capital in 2018. Prior to joining PBM Capital, Chris had an 18-year career at J.P. Morgan where he was a managing director in the Healthcare Investment Banking and Mergers and Acquisitions groups. He led the execution of a wide range of transactions including mergers and acquisitions, spin-offs and corporate separations, initial public offerings and equity and debt financings for Medical Device, Life Science Tool and Diagnostic, Pharmaceutical and Biotechnology companies. Chris graduated from Yale University with a B.A. in Ethics, Politics and Economics. We believe Mr. Martell's broad financial and investment banking experience, financial and transactional expertise and acumen in mergers and acquisitions and complex financial transactions provides him with the appropriate set of skills to serve as a member of our board of directors.

Udi Meirav, Ph.D., has served as a member of our board of directors since 2004. Dr. Meirav is the President and Founder of Boston-based EnVerid, Inc., an energy-efficiency materials company, a role he has served in since 2010 and was previously the Chief Executive Officer of Luminus Devices, Inc., a manufacturer of high performance LEDs for solid state lighting. Dr. Meirav has served on numerous boards of directors of companies involved in IT, life sciences, semiconductors and solid state lighting. He has also worked with Stata Venture Partners, an early stage venture capital fund, and with Strategic Decisions Group, a premier consulting firm with focus on pharmaceuticals and biomedical technology. Dr. Meirav has a Ph.D. in Physics from the Massachusetts Institute of Technology and a Bachelor of Science degree in Mathematics and Physics from Tel Aviv University. We believe Dr. Meirav's multidisciplinary background with executive experience in technology and finance provides him with the appropriate set of skills to serve as a member of our board of directors.

Diem Nguyen, Ph.D., MBA, will serve as a member of our board of directors upon the effectiveness of this registration statement. Dr. Nguyen is the Chief Executive Officer and member of the board of directors of Xalud Therapeutics, a private biotechnology company, which is majority-owned by PBM Capital. Previously, Dr. Nguyen was the Executive Vice President of PPD, a leading global clinical research organization providing drug development services, a position she held from April 2018 to April 2020. Since 2008, Dr. Nguyen has held various leadership roles at Pfizer Inc., last serving as Global President, Americas of Pfizer Essential Health from January 2017 to March 2018. Dr. Nguyen is a director at Verrica Pharmaceuticals Inc. (NASDAQ: VRCA) and Children's Hospital of Philadelphia. She received a B.A. in Chemistry with Specialization in Biochemistry and a Ph.D. in Biochemistry and Molecular Genetics from the University of Virginia, and an MBA in General Management from the University of Virginia's Darden Graduate School of Business Administration. We believe that Dr. Nguyen's managerial, commercial and medical experience in the pharmaceutical industry provides her with the appropriate set of skills to serve as a member of our board of directors.

Alan E. Smith, Ph.D., FRS, CBE, has served as a member of our board of directors since October 2015. Dr. Smith is the former Senior Vice President (1989-2011) and Chief Scientific Officer of Genzyme Corporation, Cambridge, MA, a position he held from 1997 to 2011. Prior to is acquisition by Genzyme in 1989, Alan was the Vice President and Scientific Director of Integrated Genetics, a Massachusetts start-up biotechnology company. Dr. Smith sits on the Scientific Advisory Board of Pharnext, a start-up genomics company in Paris, France, and he is on the Board of Directors of Arecor, a start-up biotechnology company in Cambridge UK. From 2014 to 2020, he was chairman of the Board of Cambridge in America, the representative body of the University and Colleges of Cambridge in North America, and from 2016 -2019, he was chairman of Native Plant Trust, the first plant conservation organization in the U.S. Alan has published extensively on the genetic code and protein synthesis, tumour virology, cell biology and cystic fibrosis. He holds a B.A. from Christ's College, Cambridge UK and a Ph.D. from the Laboratory of Molecular Biology, Cambridge, England. He is a fellow of the Royal Society of London and of Christ's College. We believe Dr. Smith's executive experience provides him with the appropriate set of skills to serve as a member of our board of directors.

Shaan C. Gandhi, M.D., D.Phil. has served as a member of our board of directors since May 2020. Dr. Gandhi is a Director at Northpond Ventures, LLC ("Northpond Ventures"), a global science, medical and technology-focused venture capital firm, where he leads the firm's work in biotechnologies. Previously, Shaan was a Principal at the Longwood Fund from 2018 to 2020, where he created and invested in life sciences companies, including Pyxis Oncology, a cancer immunotherapy company focused on novel modulators of the tumor microenvironment, which he

co-founded and served as President. He was an attending hospitalist at Massachusetts General Hospital from 2018 to 2019, where he also did his residency in internal medicine from 2015 to 2018. He serves on the boards of directors of various private companies, including Aro Biotherapeutics, CAMP4 Therapeutics, DiCE Molecules, StrideBio, Triumvira Immunologics and Vigil Neuroscience. He holds an M.D. from Harvard Medical School; an MBA from Harvard Business School, where he was a Baker Scholar; a D.Phil. in medical oncology from the University of Oxford, where he was a Rhodes Scholar; and a B.S. with honors in biochemistry from Case Western Reserve University. We believe that Dr. Gandhi's financial, managerial and medical experience coupled with his substantial experience as an investor in emerging biotechnology companies provides him with the appropriate set of skills to serve as a member of the board of directors.

Key Employees

Francesca Barone, M.D., Ph.D. has been Candel's Vice President, Head of Research since November 2020. Prior to that, she was our Head of Experimental Medicine since November 2020. Dr. Barone served as Head of Experimental Medicine at Kintai Therapeutics, Inc, a Flagship Pioneering, Inc. company, from May 2019 through its merger into Senda Biosciences, Inc. until November 2021. Prior to that, she was a Rheumatology Consultant and Associate Professor (Reader) at University of Birmingham and at the Birmingham, Sandwell and West Birmingham NHS Foundation Trust in UK from 2010 to May 2019. In July 2016, Dr. Barone was awarded an ARUK Senior Fellowship to exploit the mechanisms enabling the persistence of tertiary lymphoid structures (TLS) in inflamed tissue and to investigate the pathogenicity of the stromal cells in TLS associated diseases. Dr. Barone obtained her M.D. at the University of Rome, Sapienza, and her Ph.D. in immunology at Kings College in London.

Christopher Jon Matheny, PharmD, Ph.D. has been Candel's Vice President, Development Leader since March 2021. Prior to joining Candel, Dr. Matheny worked at GlaxoSmithKline in roles of increasing responsibility in translational medicine and clinical pharmacology, most recently as the Early Development Leader on four separate immuno-oncology programs from October 2013 to March 2021. Additionally, he served as the Co-chair of the Early Development Leader Community as part of the Enterprise Leadership group at GlaxoSmithKline from 2017 to 2018. He received his PharmD and Ph.D. degrees from the University of North Carolina at Chapel Hill and completed his Pharmacy Practice Residency at the University of Kentucky Hospitals.

Family Relationships

Other than Dr. Aguilar and Dr. Aguilar-Cordova, who are married, none of our directors or executive officers has a family relationship with another director or executive officer.

Composition of our Board of Directors

Our board of directors currently consists of nine members, each of whom are members pursuant to the board composition provisions of our certificate of incorporation and our voting agreement, which agreement is described under "Certain Relationships and Related Party Transactions" in this prospectus. These board composition provisions will terminate upon the completion of this offering. Upon the termination of these provisions, there will be no further contractual obligations regarding the election of our directors. Effective upon the completion of this offering, we intend to form a nominating and corporate governance committee. Our nominating and corporate governance committee and our board of directors may consider a broad range of factors relating to the qualifications and background of director nominees, which may include diversity, which is not only limited to race, gender or national origin, although we currently have no formal policy regarding board diversity. Our nominating and corporate governance committee's and our board of directors' priority in selecting board members is identification of persons who will further the interests of our stockholders through his or her established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business, understanding of the competitive landscape and professional and personal experiences and expertise relevant to our growth strategy. Our directors hold office until their successors have been elected and qualified or until the earlier of their resignation or removal. Our amended and restated certificate of incorporation and amended and restated bylaws that will become effective upon the completion of this offering also provide that our directors may be removed only for cause by the affirmative vote of the holders of at least two-thirds of the votes that all our stockholders would be entitled to cast in an annual election of directors, and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

Director independence. We intend to apply to list our common stock on The Nasdaq Global Market. Under the Nasdaq listing rules, independent directors must comprise a majority of a listed company's board of directors within twelve months from the date of listing. In addition, the Nasdaq listing rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and governance committees be independent within twelve months from the date of listing. Audit committee members must also satisfy additional independence criteria, including those set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and compensation committee members must also satisfy the independence criteria set forth in Rule 10C-1 under the Exchange Act. Under Nasdaq listing rules, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3 under the Exchange Act, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee: (1) accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries, other than compensation for board service; or (2) be an affiliated person of the listed company or any of its subsidiaries. In order to be considered independent for purposes of Rule 10C-1, the board of directors must consider, for each member of a compensation committee of a listed company, all factors specifically relevant to determining whether a director has a relationship to such company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: the source of compensation of the director, including any consulting advisory or other compensatory fee paid by such company to the director, and whether the director is affiliated with the company or any of its subsidiaries or affiliates. Our board of directors has determined that all members of the board of directors, except for Paul Peter Tak, M.D., Ph.D., FMedSci and Estuardo Aguilar-Cordova, M.D., Ph.D., are independent directors, including for purposes of the rules of the Nasdaq Global Market and the SEC.

Staggered board. In accordance with the terms of our amended and restated certificate of incorporation and amended and restated bylaws that will become effective upon the completion of this offering, our board of directors will be divided into three classes, Class I, Class II and Class III, with each class serving staggered three-year terms. At each annual meeting of the stockholders, a class of directors will be elected for a three-year term to succeed the directors of the same class whose terms are then expiring. The terms of the directors will expire upon the election and qualification of successor directors at the annual meeting of stockholders to be held during the years 2022 for Class I directors, 2023 for Class II directors and 2024 for Class III directors.

- Our Class I directors will be Shaan C. Gandhi, M.D., D.Phil, Udi Meirav, Ph.D. and Alan E Smith, Ph.D., FRS, CBE;
- Our Class II directors will be Edward J. Benz, Jr., M.D., Paul B. Manning and Paul Peter Tak, M.D., Ph.D., FMedSci; and
- Our Class III directors will be Estuardo Aguilar-Cordova, M.D., Ph.D., Chris Martell, and Diem Nguyen, Ph.D.

Our amended and restated certificate of incorporation and amended and restated bylaws that will become effective upon the completion of this offering provide that the number of directors may be changed only by resolution of our board of directors.

The division of our board of directors into three classes with staggered three-year terms may delay or prevent stockholder efforts to effect a change of our management or a change in control.

Committees of our board of directors

Our board of directors plans on establishing an audit committee, a compensation committee and a nominating and corporate governance committee, each of which will operate pursuant to a charter to be adopted by our board of directors and will be effective upon completion of the offering. Following the completion of this offering, copies of each committee's charter will be posted on the corporate governance section of our website, at *www.candeltx.com*. The inclusion of our website address in this prospectus does not incorporate by reference the information on or accessible through our website into this prospectus.

Audit committee. Effective upon completion of this offering, Shaan C. Gandhi, M.D., D.Phil, Chris Martell, and Udi Meirav, Ph.D. will serve on the audit committee, which will be chaired by Chris Martell. Our board of directors has determined that each member of the audit committee is "independent" for audit committee purposes as that term is defined in the rules of the SEC and the applicable Nasdaq Global Market rules, and has sufficient knowledge in financial and auditing matters to serve on the audit committee. Our board of directors has designated Chris Martell as an "audit committee financial expert," as defined under the applicable rules of the SEC.

The audit committee's responsibilities include:

- appointing, approving the compensation of, and assessing the independence of our independent registered public accounting firm;
- pre-approving auditing and permissible non-audit services, and the terms of such services, to be provided by our independent registered public accounting firm;
- reviewing the overall audit plan with our independent registered public accounting firm and members of management responsible for preparing our financial statements;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures as well as critical accounting policies and practices used by us;
- coordinating the oversight and reviewing the adequacy of our internal control over financial reporting;
- establishing policies and procedures for the receipt, retention and treatment of accounting-related complaints and concerns;
- recommending based upon the audit committee's review and discussions with management and our independent registered public accounting firm whether our audited financial statements shall be included in our Annual Report on Form 10-K;
- monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to our financial statements and accounting matters;
- preparing the audit committee report required by SEC rules to be included in our annual proxy statement;
- reviewing all related person transactions for potential conflict of interest situations and approving all such transactions; and
- reviewing quarterly earnings releases and scripts.

Compensation committee. Effective upon completion of this offering, Paul B. Manning, Chris Martell and Alan E. Smith, Ph.D., FRS, CBE will serve on the compensation committee, which will be chaired by Chris Martell. Our board of directors has determined that each member of the compensation committee is "independent" as defined in the applicable Nasdaq Global Market rules. The compensation committee's responsibilities include:

- annually reviewing and recommending corporate goals and objectives relevant to the compensation of our Chief Executive Officer to our board of directors;
- evaluating the performance of our Chief Executive Officer in light of such corporate goals and objectives and, based on such evaluation, recommending to our board of directors for determination the compensation of our Chief Executive Officer;
- reviewing and approving the compensation of our other executive officers;
- reviewing and establishing our overall management compensation, philosophy and policy;
- overseeing and administering our compensation and similar plans;
- evaluating and assessing potential and current compensation advisors in accordance with the independence standards identified in the applicable Nasdaq Global Market rules;
- retaining and approving the compensation of any compensation advisors;
- reviewing and approving our policies and procedures for the grant of equity-based awards;
- reviewing and making recommendations to the board of directors with respect to director compensation; and
- reviewing and discussing with management the compensation discussion and analysis to be included in our annual proxy statement or Annual Report on Form 10-K.

Nominating and corporate governance committee. Effective upon completion of this offering, Estuardo Aguilar-Cordova, M.D., Ph.D., Edward J. Benz, Jr., M.D. and Shaan Gandhi, M.D., D.Phil will serve on the nominating and corporate governance committee, which will be chaired by Edward J. Benz, Jr., M.D. Our board of directors has determined that Edward J. Benz, Jr., M.D. and Shaan Gandhi, M.D., D.Phil, satisfy the relevant independence requirements for service on the nominating and corporate governance committee set forth in the Nasdaq Global Market listing rules. Due to being our Chief Scientific Officer, Estuardo Aguilar-Cordova, M.D., Ph.D., is not independent for purposes of nominating and corporate governance committee membership under the Nasdaq Global Market listing rules. Under the applicable Nasdaq Global Market listing rules, we are permitted to phase-in our compliance with the independence requirements for our nominating and corporate governance committee. The phase-in periods with respect to director independence allow us to have only one independent member on our nominating and corporate governance committee upon the listing date of our common stock, a majority of independent members on our nominating and corporate governance committee within 90 days of the listing date and a fully independent nominating and corporate governance committee within one year of the listing date. We are taking advantage of these phase-in rules with respect to Dr. Aguilar-Cordova's service on our nominating and corporate governance committee, and we expect that by the first anniversary of our listing on the Nasdaq Global Market, our nominating and corporate governance committee will comply with the applicable independence requirements. The nominating and corporate governance committee's responsibilities include:

- developing and recommending to the board of directors criteria for board and committee membership;
- establishing procedures for identifying and evaluating board of director candidates, including nominees recommended by stockholders;
- identifying individuals qualified to become members of the board of directors;
- recommending to the board of directors the persons to be nominated for election as directors and to each of the board's committees;
- reviewing and discussing with the board of directors the corporate succession plans for the Chief Executive Officer and other key officers;
- developing and recommending to the board of directors a set of corporate governance guidelines; and
- overseeing the evaluation of the board of directors and management.

Our board of directors may from time to time establish other committees.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee has at any time during the prior three years been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving on our board of directors or compensation committee.

Corporate Governance

We plan to adopt a code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting, which will be effective upon completion of this offering. Upon the completion of this offering, our code of business conduct and ethics will be available on our website at *www.candeltx.com*. The inclusion of our website address in this prospectus does not incorporate by reference the information on or accessible through our website into this prospectus. We intend to disclose any substantive amendments to the code, or grant of any waivers from the code for any officer or director, on our website or in a Current Report on Form 8-K.

Limitations on Liability and Indemnification Agreements

As permitted by Delaware law, provisions in our amended and restated certificate of incorporation, which will become effective immediately prior to the closing of this offering, and amended and restated bylaws, which will become effective upon the effectiveness of this registration statement, limit or eliminate the personal liability of directors for a breach of their fiduciary duty of care as a director. The duty of care generally requires that, when acting on behalf of the corporation, a director exercise an informed business judgment based on all material

information reasonably available to him or her. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any act related to unlawful stock repurchases, redemptions or other distributions or payments of dividends; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not limit or eliminate our rights or any stockholder's rights to seek non-monetary relief, such as injunctive relief or rescission. These provisions will not alter a director's liability under other laws, such as the federal securities laws or other state or federal laws. Our amended and restated certificate of incorporation that will become effective immediately prior to the closing of this offering also authorizes us to indemnify our officers, directors and other agents to the fullest extent permitted under Delaware law.

As permitted by Delaware law, our amended and restated bylaws to be effective upon the effectiveness of this registration statement will provide that:

- we will indemnify our directors, officers, employees and other agents to the fullest extent permitted by law;
- we must advance expenses to our directors and officers, and may advance expenses to our employees and other agents, in connection with a legal proceeding to the fullest extent permitted by law; and
- the rights provided in our amended and restated bylaws are not exclusive.

If Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director or officer, then the liability of our directors or officers will be so eliminated or limited to the fullest extent permitted by Delaware law, as so amended. Our amended and restated bylaws will also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in connection with their services to us, regardless of whether our bylaws permit such indemnification. We have obtained such insurance.

In addition to the indemnification that will be provided for in our amended and restated certificate of incorporation and amended and restated bylaws, we plan to enter into separate indemnification agreements with each of our directors and executive officers, which may be broader than the specific indemnification provisions contained in the Delaware General Corporation Law. These indemnification agreements may require us, among other things, to indemnify our directors and executive officers for some expenses, including attorneys' fees, expenses, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of his service as one of our directors or executive officers or any other company or enterprise to which the person provides services at our request. We believe that these provisions and agreements are necessary to attract and retain qualified individuals to serve as directors and executive officers.

This description of the indemnification provisions of our amended and restated certificate of incorporation, our amended and restated bylaws and our indemnification agreements is qualified in its entirety by reference to these documents, each of which is attached as an exhibit to the registration statement of which this prospectus forms a part.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable.

There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

Board Leadership Structure and Board's Role in Risk Oversight

Our board of directors has no policy with respect to the combination or separation of the position of Chairman of the Board and Chief Executive Officer. Our board of directors recognizes that no single leadership model is correct at all

times and that, depending on the circumstances, another leadership model might be appropriate. Our board of directors, therefore, believes that it should have the flexibility to decide whether it is best for our Company at any point in time to combine or separate the roles of Chief Executive Officer and Chairman of the Board.

Risk is inherent with every business, and how well a business manages risk can ultimately determine its success. We face a number of risks, including risks relating to our operations, strategic direction and intellectual property as more fully discussed under “Risk Factors” in this prospectus. Management is responsible for the day-to-day management of risks we face, while our board of directors, as a whole and through its committees, has responsibility for the oversight of risk management. In its risk oversight role, our board of directors has the responsibility to satisfy itself that the risk management processes designed and implemented by management are adequate and functioning as designed.

The role of the board of directors in overseeing the management of our risks is conducted primarily through committees of the board of directors, as disclosed in the descriptions of each of the committees above and in the charters of each of the committees. The full board of directors (or the appropriate board committee in the case of risks that are under the purview of a particular committee) discusses with management our major risk exposures, their potential impact on us, and the steps we take to manage them. When a board committee is responsible for evaluating and overseeing the management of a particular risk or risks, the chair of the relevant committee reports on the discussion to the full board of directors during the committee reports portion of the next board meeting. This enables the board of directors and its committees to coordinate the risk oversight role, particularly with respect to risk interrelationships.

EXECUTIVE COMPENSATION

The following discussion contains forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. The actual amount and form of compensation and the compensation policies and practices that we adopt in the future may differ materially from currently planned programs as summarized in this discussion.

Our named executive officers, or NEOs, for the year ended December 31, 2020, which consist of each person who served as our principal executive officer during 2020 and the next two most highly compensated executive officers, are:

- Paul Peter Tak, M.D., Ph.D., FMedSci, our President and Chief Executive Officer;
- Estuardo Aguilar-Cordova, M.D., Ph.D., our Founder, Chief Scientific Officer and former Chief Executive Officer;
- Laura K. Aguilar, M.D., Ph.D., our Chief Medical Officer; and
- John Canepa, our Chief Financial Officer.

Executive Compensation Overview

To date, the compensation of our NEOs has consisted of a combination of base salary, cash bonuses and long-term incentive compensation in the form of stock options. Our NEOs, like all full-time employees, are eligible to participate in our health and welfare benefit plans. As we transition from a private company to a publicly traded company, we intend to evaluate our compensation values and philosophy and compensation plans and arrangements as circumstances require. At a minimum, we expect to review executive compensation annually with input from a compensation consultant. As part of this review process, we expect the board of directors and the compensation committee to apply our values and philosophy, while considering the compensation levels needed to ensure our executive compensation program remains competitive. We will also review whether we are meeting our retention objectives and the potential cost of replacing a key employee.

2020 Summary Compensation Table

The following table shows total compensation earned by or paid to our NEOs for services rendered to us in all capacities during the fiscal year ended December 31, 2020.

Name and Principal Position	YEAR	SALARY ($)	BONUS ($) [1]	STOCK AWARDS ($) [2]	OPTION AWARDS ($) [2]	NON-EQUITY INCENTIVE PLAN COMPENSATION ($) [3]	ALL OTHER COMPENSATION ($)	TOTAL ($)
Paul Peter Tak, M.D., Ph.D., FMedSci *President and Chief Executive Officer*	2020	134,615	85,000	—	2,316,446	90,450	—	2,626,511
Estuardo Aguilar-Cordova, M.D., Ph.D. *Founder & Chief Scientific Officer; Former Chief Executive Officer*	2020	444,903	104,000	—	—	191,250	—	740,153
Laura K. Aguilar, M.D., Ph.D. *Chief Medical Officer*	2020	399,423	—	—	—	160,000	—	559,423
John Canepa *Chief Financial Officer*	2020	14,231	75,000	—	1,230,085	—	—	1,319,316

(1) The amounts reported in this column reflect the first two $42,500 installments of a $170,000 total sign-on bonus pursuant to Dr. Tak's employment agreement with the Company, payable in four quarterly installments following September 12, 2020, a $104,000 discretionary bonus paid to Dr. Aguilar-Cordova for performance in 2020, and a $75,000 sign-on bonus paid to Mr. Canepa pursuant to his employment agreement with the Company.

(2) In accordance with SEC rules, these columns reflect the aggregate grant date fair value of the option awards and stock awards granted during 2020 computed in accordance with Financial Accounting Standard Board ASC Topic 718 for stock-based compensation transactions, or ASC 718. Assumptions used in the calculation of these amounts are included in Note 11 to our financial statements included elsewhere in this prospectus. These amounts do not reflect the actual economic value that will be realized by the named executive officer upon the vesting of stock options, the exercise of stock options, the lapse of our repurchase option on shares of restricted stock or the sale of shares of our common stock. Dr. Tak was granted a performance-based stock option of 296,144 shares in 2020 and was granted an option to purchase 1,776,868 shares of common stock in connection with his employment agreement. No amount has been included in the table above as there was no value ascribed based upon probable achievement. Assuming maximum achievement, the grant date fair value of such performance-based award to Dr. Tak is $395,883. Mr. Canepa was granted an option to purchase 322,710 shares of common stock in connection with his employment agreement.

(3) Cash bonuses for performance during the year ended December 31, 2020 are not calculable as of the latest practicable date prior to the filing of this prospectus. We expect that such amounts will be determined later in the first quarter of 2021. For more information on these bonuses, see the description of the annual performance bonuses under “2020 bonuses” below.

Narrative to Summary Compensation Table

2020 salaries

Our NEOs each receive a base salary to compensate them for services rendered to our company. The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive’s skill set, experience, role and responsibilities. Base salaries are reviewed annually, typically in connection with our annual performance review process, approved by our board of directors or the compensation committee, and may be adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance, and experience.

For fiscal year 2020, the annual base salary for each of Dr. Tak, Dr. Aguilar-Cordova, Dr. Aguilar and Mr. Canepa were $500,000, $500,000, $395,000, and 370,000, respectively.

2020 bonuses

For the fiscal year ended December 31, 2020, each of the named executive officers was eligible to earn an annual cash bonus based on the achievement of certain corporate and individual performance milestones. The target annual bonus for each of Dr. Tak, Dr. Aguilar-Cordova, Dr. Aguilar, and Mr. Canepa for the fiscal year ended December 31, 2020 were 50%, 50%, 40% and 40% of annual base salary, respectively.

Equity-based compensation

Although we do not have a formal policy with respect to the grant of equity incentive awards to our executive officers, we believe that equity grants provide our executives with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and our stockholders. In addition, we believe that equity grants promote executive retention because they incentivize our executive officers to remain in our employment during the vesting period. Accordingly, our board of directors or our compensation committee periodically review the equity incentive compensation of our named executive officers and may grant equity incentive awards to them from time to time.

In 2020, we granted an option to purchase 1,776,868 shares of our common stock, subject to time-based vesting and an option to purchase 296,144 shares of our common stock, subject to performance-based vesting, to Dr. Tak in connection with his appointment as our President and Chief Executive Officer. In 2020, we also granted options to purchase 322,710 shares of our common stock to Mr. Canepa in connection with his appointment as our Chief Financial Officer.

Employment Agreements in Place During Fiscal Year 2020 for Our Named Executive Officers

Paul Peter Tak, M.D., Ph.D, FMedSci.

Effective September 12, 2020, we entered into an employment agreement with Dr. Tak, or the Tak Employment Agreement, for the position of President and Chief Executive Officer. The Tak Employment Agreement provides for an annual base salary and an annual bonus opportunity. Pursuant to the Tak Employment Agreement Dr. Tak’s annual base salary will increase to $670,000 per year effective on the first anniversary of the commencement of his employment if the Company has completed an underwritten public offering on or prior to such date. The Tak Employment Agreement provides for a signing bonus in the gross amount of $170,000, payable in four equal

quarterly installments of $42,500 each, commencing on the first payroll date following the commencement of his employment and on each 3-month anniversary of employment following his start date, provided that he remains employed through each date of payment. Pursuant to the Tak Employment Agreement, Dr. Tak is eligible to receive a lump sum payment of $80,000 to assist with relocation to the Greater Boston Area if and when he relocates in 2022, subject to repayment if Dr. Tak terminates his employment other than for "good reason" or we terminate his employment for "cause" (as such terms are defined in the Tak Employment Agreement) within 12 months of receipt of the relocation assistance payment. Pursuant to the Tak Employment Agreement, we will reimburse Dr. Tak for reasonable costs related to travel to Massachusetts and temporary housing in Massachusetts, not to exceed $20,000, which amount will be grossed up in respect of any related taxes, reasonable legal fees related to obtaining a visa, reasonable fees for independent tax and accounting advise not to exceed $10,000 per year, and reasonable legal fees related to negotiation of his employment agreement, not to exceed $10,000. Dr. Tak is eligible to participate in the employee benefit plans available to our employees, subject to the terms of those plans.

Pursuant to the Tak Employment Agreement, in the event that Dr. Tak's employment is terminated by us without cause or by Dr. Tak for good reason outside of the 3 month period preceding and 12 month period following the first event constituting a change in control (such period, the "change in control period"), subject to the execution and effectiveness of a severance and release of claims agreement within 60 days of such termination, he will be entitled to receive (i) an amount equal to 12 months of base salary plus Dr. Tak's target bonus for the then-current year, less any payments Dr. Tak receives pursuant to his restrictive covenants agreement with the Company, payable in installments over 12 months commencing within 60 days of termination, and (ii) subject to the Dr. Tak's timely election to continue COBRA health coverage and copayment of premium amounts at the applicable active employees' rate, we will continue to pay the share of the premiums that we would have paid to provide health insurance to Dr. Tak until the earlier of (A) 12 months following termination or (B) Dr. Tak's eligibility for group medical plan benefits under any other employer's group medical plan. In the event that such termination occurs during the change in control period, Dr. Tak will, subject to the execution and effectiveness of a general severance and release of claims agreement within 60 days of such termination, be entitled to receive (x) a lump sum payment equal to 1.5 times the sum of Dr. Tak's then-current base salary (or base salary in effect immediately prior to the change in control, if higher), plus his target bonus for the then-current year (or his target bonus in effect immediately prior to the change in control, if higher), less any payments pursuant to Dr. Tak receives pursuant to his restrictive covenants agreement with the Company, and (y) the benefits set forth in clause (ii) of the preceding sentence but for a period of 18 months. In addition, pursuant to the Tak Employment Agreement, all equity awards held by Dr. Tak that are subject to time based vesting will fully accelerate as of the earlier of the consummation of a "change in control" of the Company (as defined in the Tak Employment Agreement) or the termination of Dr. Tak's employment by the Company without cause or by Dr. Tak for good reason. Furthermore, in the event of a change of control or Dr. Tak's termination without cause or for good reason, Dr. Tak will have no less than 12 months to exercise vested, unexpired stock options.

Estuardo Aguilar-Cordova, M.D., Ph.D.

Effective November 13, 2018, we entered into an amended and restated employment agreement with Dr. Aguilar-Cordova, or the Estuardo Aguilar-Cordova Employment Agreement, for the position of President and Chief Executive Officer. Dr. (Estuardo) Aguilar-Cordova subsequently transitioned to his current role as our Chief Scientific Officer in September 2020. The Estuardo Aguilar-Cordova Employment Agreement provides for an annual base salary and an annual target bonus opportunity. Dr. Aguilar-Cordova is eligible to participate in the employee benefit plans available to our employees, subject to the terms of those plans.

Pursuant to the Estuardo Aguilar-Cordova Employment Agreement, in the event that Dr. Aguilar-Cordova's employment is terminated by us without "cause" or by Dr. Aguilar-Cordova for "good reason" (as such terms are defined in the Estuardo Aguilar-Cordova Employment Agreement), subject to the execution and effectiveness of a severance and release of claims agreement, he will be entitled to receive (i) 12 months of base salary continuation, and (ii) subject to Dr. Aguilar-Cordova's timely election to continue COBRA health coverage, we will pay the premiums necessary to continue Dr. Aguilar-Cordova's and his covered dependents' health insurance coverage until the earlier of (A) 12 months following termination or (B) Dr. Aguilar-Cordova's eligibility for group medical plan benefits under any other employer's group medical plan.

Laura K. Aguilar, M.D., Ph.D.

Effective November 13, 2018, we entered into an amended and restated employment agreement with Dr. Aguilar, or the Laura Aguilar Employment Agreement, for the position of Chief Medical Officer. The Laura Aguilar Employment Agreement provides for an annual base salary an annual target bonus opportunity. Dr. Aguilar is eligible to participate in the employee benefit plans available to our employees, subject to the terms of those plans.

Pursuant to the Laura Aguilar Employment Agreement, in the event that Dr. Aguilar's employment is terminated by us without "cause" or by Dr. Aguilar for "good reason" (as such terms are defined in the Laura Aguilar Employment Agreement), subject to the execution and effectiveness of a severance and release of claims agreement, she will be entitled to receive (i) 12 months of base salary continuation, and (ii) subject to Dr. Aguilar's timely election to continue COBRA health coverage, we will pay the premiums necessary to continue Dr. Aguilar's and her covered dependents' health insurance coverage until the earlier of (A) 12 months following termination or (B) Dr. Aguilar's eligibility for group medical plan benefits under any other employer's group medical plan.

John Canepa

Effective December 1, 2020, we entered into an employment agreement with Mr. Canepa, or the Canepa Employment Agreement, for the position of Chief Financial Officer. The Canepa Employment Agreement provides for an annual base salary and an annual target bonus opportunity. Pursuant to the Canepa Employment Agreement Mr. Canepa received a signing bonus in the gross amount of $75,000, which is subject to repayment if Mr. Canepa voluntarily terminates his employment with the Company or if the Company terminates his employment for reasons excluding redundancy, ill health or a transfer of the part of the business in which he works within 12 months of the commencement of his employment. Mr. Canepa is eligible to participate in the employee benefit plans available to our employees, subject to the terms of those plans.

Pursuant to the Canepa Employment Agreement, in the event that Mr. Canepa's employment is terminated by us without cause or by Mr. Canepa for good reason, subject to the execution and effectiveness of a severance and release of claims agreement within 60 days of such termination, he will be entitled to receive (i) an amount equal to nine months of base salary plus Mr. Canepa's target bonus for the then-current year, less any payments Mr. Canepa receives pursuant to his restrictive covenants agreement with the Company, payable in installments over 9 months commencing within 60 days of termination, and (ii) subject to the Mr. Canepa's timely election to continue COBRA health coverage and copayment of premium amounts at the applicable active employees' rate, we will continue to pay the share of the premiums that we would have paid to provide health insurance to Mr. Canepa until the earlier of (A) nine months following termination or (B) Mr. Canepa's eligibility for group medical plan benefits under any other employer's group medical plan. Pursuant to the Canepa Employment Agreement, all equity awards held by Mr. Canepa that are subject to time based vesting will fully accelerate if Mr. Canepa's employment is terminated by the Company without "cause" or by Mr. Canepa for "good reason" within one month prior to or 12 months following the consummation of a "change in control" (as such terms are defined in the Canepa Employment Agreement).

Outstanding Equity Awards at Fiscal Year End

The following table presents the outstanding equity awards held by each of our named executive officers as of December 31, 2020:

		OPTION AWARDS (1)					STOCK AWARDS	
Name	VESTING COMMENCEMENT DATE	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS (#) EXERCISABLE	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS (#) UNEXERCISABLE	EQUITY INCENTIVE PLAN AWARDS: NUMBER OF SECURITIES UNDERLYING UNEXERCISED UNEARNED OPTIONS (#)	OPTION EXERCISE PRICE ($)	OPTION EXPIRATION DATE	NUMBER OF SHARES THAT HAVE NOT VESTED (#)	MARKET VALUE OF SHARES THAT HAVE NOT VESTED ($)
Paul Peter Tak, M.D., Ph.D., FMedSci	9/14/2020	444,217	1,332,651 (2)	—	1.55	10/9/2030	—	—
President and Chief Executive Officer		—	—	296,144 (3)	1.55	10/9/2030	—	—
Estuardo Aguilar-Cordova, M.D., Ph.D.	10/13/2018	38,358	38,358 (4)	—	1.46	11/12/2028	—	—
Founder & Chief Scientific Officer; Former Chief Executive Officer		—	—	76,717 (5)	1.46	11/12/2028	—	—
	1/1/2019	6,103	6,103 (6)	—	1.46	8/17/2028	—	—
Laura K. Aguilar, M.D., Ph.D.	10/13/2018	38,358	38,358 (4)	—	1.46	11/12/2028	—	—
Chief Medical Officer		—	—	76,717 (5)	1.46	11/12/2028	—	—
	1/1/2019	8,950	8,950 (6)	—	1.46	8/17/2028	—	—
John Canepa	12/1/2020	—	322,710 (7)	—	1.55	12/14/2030	—	—
Chief Financial Officer								

(1) Each of the outstanding equity awards in the table above was granted pursuant to our 2015 Stock Plan, as amended, or the 2015 Plan.

(2) The shares underlying this option vest as follows: 25% vested upon the grant date, 25% vesting on the first anniversary of the vesting commencement date, and the remainder vesting thereafter in 36 equal monthly installments.

(3) The shares underlying this option shall vest (if at all) if a specified stock price following our initial public offering is obtained on or prior to September 12, 2023.

(4) The shares underlying this option vest in four equal annual installments following the vesting commencement date.

(5) The shares underlying this option shall vest upon achievement of a specified clinical milestone on or prior to November 12, 2023.

(6) The shares underlying this option vest as follows: 25% upon the grant date the remainder in three equal annual installments following the vesting commencement date.

(7) The shares underlying this option vest as follows: 35% vest on the first anniversary of the vesting commencement date, 35% vest in equal monthly installments over months 13 to 24 following the vesting commencement date, 15% vest in equal monthly installments over months 25 to 36 following the vesting commencement date, and 15% vest in equal monthly installments over months 37 to 48 following the vesting commencement date.

Director Compensation

The following table provides certain information concerning compensation for each person who served as a non-employee member of our board of directors during the year ended December 31, 2020. Other than as set forth in the table and described more fully below, we did not pay any compensation, make any equity awards or non-equity awards to, or pay any other compensation to any of the non-employee members of our board of directors in 2020. During fiscal year 2020, Paul Peter Tak, M.D., Ph.D., FMedSci, our President and Chief Executive Officer, and Estuardo Aguilar-Cordova, M.D., Ph.D., our Founder, Chief Scientific Officer, and former President and Chief Executive Officer, served as members of our board of directors and received no additional compensation for their

services as members of our board of directors. See the section titled “Executive Compensation” for more information about Dr. Tak’s and Dr. Aguilar-Cordova’s compensation for fiscal year 2020. We reimburse non-employee members of our board of directors for reasonable travel and out-of-pocket expenses incurred in attending meetings of our board of directors and committees of our board of directors.

Name	FEES EARNED OR PAID IN CASH ($)	STOCK AWARDS ($) (1)	OPTION AWARDS ($) (1)	ALL OTHER COMPENSATION ($)	TOTAL ($)
Edward J. Benz, Jr., M.D.	—	—	60,149	—	60,149
Shaan C. Gandhi, M.D., D.Phil (2)	—	—	—	—	—
Paul B. Manning	—	—	—	—	—
Chris Martell	—	—	60,149	—	60,149
Udi Meirav, Ph.D.	—	—	60,149	—	60,149
Alan E. Smith, Ph.D., FRS, CBE	—	—	60,149	—	60,149

(1) In accordance with SEC rules, these columns reflect the aggregate grant date fair value of the option awards granted during 2020 computed in accordance with Financial Accounting Standard Board ASC Topic 718 for stock-based compensation transactions, or ASC 718. Assumptions used in the calculation of these amounts are included in Note 2 to our financial statements included elsewhere in this prospectus. As of December 31, 2020, our non-employee directors each held options to purchase shares of our common stock and stock awards as follows: Dr. Benz held options to purchase 52,890 shares, Mr. Martell held options to purchase 16,274 shares, Dr. Meirav held options to purchase 99,677 shares, and Dr. Smith held options to purchase 20,342 shares.

(2) Dr. Gandhi disclaimed director compensation in connection with service on our board of directors in accordance with the standard policy of Northpond Ventures.

Non-Employee Director Compensation Policy

Our board of directors intends to adopt a non-employee director compensation policy, which will be effective as of the completion of this offering, that is designed to enable us to attract and retain, on a long-term basis, highly qualified non-employee directors. Under the policy, each director who is not an employee will be paid cash compensation from and after the completion of this offering, as set forth below:

	ANNUAL RETAINER
Board of Directors:	
All non-employee members (1)	$ 35,000
Audit Committee:	
Chair	$ 15,000
Members	$ 7,500
Compensation Committee:	
Chair	$ 10,000
Members	$ 5,000
Nominating and Corporate Governance Committee:	
Chair	$ 8,000
Members	$ 4,000

(1) Dr. Gandhi disclaims director compensation in connection with service on our board of directors in accordance with the standard policy of Northpond Ventures.

In addition, each non-employee director will be granted a non-qualified stock option to purchase 28,480 shares of common stock on the date of such director’s election or appointment to the board of directors, which will vest monthly over three years, subject to continued service as a director. On the date of each annual meeting of stockholders of our company, each continuing non-employee director, other than a director receiving an initial equity award, will be granted a non-qualified stock option to purchase 14,240 shares of common stock, which will vest and become fully exercisable upon the earlier to occur of the first anniversary of the grant date or the date of the next annual meeting of stockholders following the date of grant, subject to continued service as a director through such date.

Compensation Risk Assessment

We believe that although a portion of the compensation provided to our executive officers and other employees is performance-based, our executive compensation program does not encourage excessive or unnecessary risk taking. This is primarily due to the fact that our compensation programs are designed to encourage our executive officers and other employees to remain focused on both short-term and long-term strategic goals, in particular in connection with our pay-for-performance compensation philosophy. As a result, we do not believe that our compensation programs are reasonably likely to have a material adverse effect on our company.

Compensation Plans

2015 Stock Plan

The 2015 Stock Plan, or the 2015 Plan, was approved by our board of directors and our stockholders on October 21, 2015 and amended in November 2018, October 2020, December 2020, March 2021, April 2021 and June 2021. Under the 2015 Plan, 5,336,262 shares of common stock have been reserved for issuance in the form of incentive stock options, non-qualified stock options, restricted stock, unrestricted stock or any combination of the foregoing. The shares issuable pursuant to awards granted under the 2015 Plan are authorized but unissued shares.

The 2015 Plan is administered by our board or at the discretion of the board, which has full power to select the individuals to whom awards will be granted and to determine the specific terms and conditions of each award, subject to the provisions of the 2015 Plan. Pursuant to the 2015 Plan and subject to applicable law, our board of directors has delegated to the compensation committee the power to make recommendations to the board of directors relating to management compensation, the adoption of employee benefit plans, stock option or equity incentive plans and other similar matters.

The option exercise price of each option granted under the 2015 Plan is determined by our board of directors and may not be less than the fair market value of a share of common stock on the date of grant. The term of each option is fixed by the board and may not exceed 10 years from the date of grant. The board determines at what time or times each option may be exercised when granting the option.

The 2015 Plan provides that, upon the consummation of a sale event, unless provision is made in connection with the sale event for the assumption or continuation of the awards by the successor entity or substitution of the awards with new awards of the successor entity, with appropriate adjustment, the 2015 Plan and all outstanding and unexercised options issued thereunder will terminate upon the effective time of the sale event. We may make or provide for cash payment to holders of options equal to the difference between (i) the per share cash consideration in the sale event multiplied by the number of shares subject to outstanding options being cancelled, and (ii) the aggregate exercise price to the holders of all vested and exercisable options.

Our board of directors may amend the 2015 Plan but no such action may adversely affect the rights of an award holder without such holder's consent. Approval by our stockholders of amendments to the 2015 Plan must be obtained if required by law.

As of March 31, 2021, options to purchase 4,079,006 shares of common stock were outstanding under the 2015 Plan. Our board of directors has determined not to make any further awards under the 2015 Plan following the closing of this offering.

2021 Stock Option and Incentive Plan

Our 2021 Plan, was adopted by our board of directors on July 10, 2021, approved by our stockholders on July 14, 2021 and will become effective upon the date immediately preceding the date on which the registration statement of which this prospectus is part is declared effective by the SEC. The 2021 Plan will replace the 2015 Plan as our board of directors has determined not to make additional awards under the 2015 Plan following the closing of our initial public offering. However, the 2015 Plan will continue to govern outstanding equity awards granted thereunder. The 2021 Plan allows us to make equity-based and cash-based incentive awards to our officers, employees, directors and consultants.

We have initially reserved 2,054,000 shares of our common stock for the issuance of awards under the 2021 Plan, or the Initial Limit. The 2021 Plan provides that the number of shares reserved and available for issuance under the

2021 Plan will automatically increase on January 1, 2022 and each January 1 thereafter, by 4% of the outstanding number of shares of our common stock on the immediately preceding December 31 or such lesser number of shares as determined by our compensation committee, or the Annual Increase. The number of shares reserved under the 2021 Plan subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization.

The shares we issue under the 2021 Plan will be authorized but unissued shares or shares that we reacquire. The shares of common stock underlying any awards under the 2021 Plan and the 2015 Plan that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without the issuance of stock, expire or are otherwise terminated (other than by exercise) will be added back to the shares of common stock available for issuance under the 2021 Plan.

The maximum number of shares of common stock that may be issued in the form of incentive stock options shall not exceed the Initial Limit, cumulatively increased on January 1, 2022 and on each January 1 thereafter by the lesser of the Annual Increase for such year or shares of common stock.

The grant date fair value of all awards made under our 2021 Plan and all other cash compensation paid by us to any non-employee director in any calendar year for services as a non-employee director shall not exceed $750,000; provided, however, that such amount shall be $1,000,000 for the calendar year in which the applicable non-employee director is initially elected or appointed to the board of directors.

The 2021 Plan will be administered by our compensation committee. Our compensation committee has the full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted and the number of shares subject to such awards, to make any combination of awards to participants, to accelerate at any time the exercisability or vesting of any award and to determine the specific terms and conditions of each award, subject to the provisions of the 2021 Plan. Persons eligible to participate in the 2021 Plan will be those full or part-time officers, employees, non-employee directors and consultants as selected from time to time by our compensation committee in its discretion.

The 2021 Plan permits the granting of both options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code and options that do not so qualify. The option exercise price of each option will be determined by our compensation committee but may not be less than 100% of the fair market value of our common stock on the date of grant unless the option is granted (i) pursuant to a transaction described in, and in a manner consistent with Section 424(a) of the Code or (ii) to individuals who are not subject to U.S. income tax. The term of each option will be fixed by our compensation committee and may not exceed 10 years from the date of grant. Our compensation committee will determine at what time or times each option may be exercised.

Our compensation committee may award stock appreciation rights under the 2021 Plan subject to such conditions and restrictions as it may determine. Stock appreciation rights entitle the recipient to shares of common stock, or cash, equal to the value of the appreciation in our stock price over the exercise price. The exercise price of each stock appreciation right may not be less than 100% of the fair market value of our common stock on the date of grant. The term of each stock appreciation right will be fixed by our compensation committee and may not exceed 10 years from the date of grant. Our compensation committee will determine at what time or times each stock appreciation right may be exercised.

Our compensation committee may award restricted shares of common stock and restricted stock units to participants subject to such conditions and restrictions as it may determine. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment with us through a specified vesting period. Our compensation committee may also grant shares of common stock that are free from any restrictions under the 2021 Plan. Unrestricted stock may be granted to participants in recognition of past services or for other valid consideration and may be issued in lieu of cash compensation due to such participant.

Our compensation committee may grant dividend equivalent rights to participants that entitle the recipient to receive credits for dividends that would be paid if the recipient had held a specified number of shares of common stock.

Our compensation committee may grant cash bonuses under the 2021 Plan to participants, subject to the achievement of certain performance goals.

The 2021 Plan provides that upon the effectiveness of a "sale event," as defined in the 2021 Plan, an acquirer or successor entity may assume, continue or substitute outstanding awards under the 2021 Plan. To the extent that awards granted under the 2021 Plan are not assumed or continued or substituted by the successor entity, upon the effective time of the sale event, such awards shall terminate. In such case, except as may be otherwise provided in the relevant award certificate, all awards with time-based vesting, conditions or restrictions shall become fully vested and nonforfeitable as of the effective time of the sale event and all awards with conditions and restrictions relating to the attainment of performance goals may become vested and nonforfeitable in connection with a sale event in the administrator's discretion or to the extent specified in the relevant award certificate. In the event of such termination, (i) individuals holding options and stock appreciation rights will be permitted to exercise such options and stock appreciation rights (to the extent exercisable) within a specified period of time prior to the sale event or (ii) we may make or provide for a payment, in cash or in kind, to participants holding vested and exercisable options and stock appreciation rights equal to the difference between the per share consideration payable to stockholders in the sale event and the exercise price of the options or stock appreciation rights and we may make or provide for a payment, in cash or in kind, to participants holding other vested awards.

Our board of directors may amend or discontinue the 2021 Plan and our compensation committee may amend or cancel outstanding awards for purposes of satisfying changes in law or any other lawful purpose, but no such action may adversely affect rights under an award without the holder's consent. Certain amendments to the 2021 Plan require the approval of our stockholders. The administrator of the 2021 Plan is specifically authorized to exercise its discretion to reduce the exercise price of outstanding stock options and stock appreciation rights or effect the repricing of such awards through cancellation and re-grants without stockholder consent. No awards may be granted under the 2021 Plan after the date that is 10 years from the effective date of the 2021 Plan. No awards under the 2021 Plan have been made prior to the date of this prospectus.

2021 Employee Stock Purchase Plan

Our Employee Stock Purchase Plan, or ESPP, was adopted by our board of directors on July 10, 2021, approved by our stockholders on July 14, 2021 and will become effective on the date immediately preceding the date on which the registration statement of which this prospectus forms a part is declared effective by the SEC. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Code. The ESPP initially reserves and authorizes the issuance of up to a total of 293,000 shares of our common stock to participating employees. The ESPP provides that the number of shares reserved and available for issuance will automatically increase on January 1, 2022 and each January 1 thereafter through January 1, 2031, by the least of (i) 293,000 shares of our common stock, (ii) 1% of the outstanding number of shares of common stock on the immediately preceding December 31, or (iii) such lesser number of shares of common stock as determined by the administrator of the ESPP. The number of shares reserved under the ESPP is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization.

All employees who are customarily employed by us or one of our designated subsidiaries for more than 20 hours per week and who we have employed for a period of time as required by the administrator of the ESPP (but in no event will the required period of continuous employment be equal or greater than two years) are eligible to participate in the ESPP. However, any employee who owns 5% or more of the total combined voting power or value of all classes of our stock will not be eligible to purchase shares of common stock under the ESPP.

We may make one or more offerings each year to our employees to purchase shares under the ESPP. Each eligible employee may elect to participate in any offering by submitting an enrollment form at least 15 business days before the applicable offering date.

Each employee who is a participant in the ESPP may purchase shares of our common stock by authorizing payroll deductions of up to 15% of his or her eligible compensation during an offering period. Unless the participating employee has previously withdrawn from the offering, his or her accumulated payroll deductions will be used to purchase shares of our common stock on the last business day of the offering period at a price equal to 85% of the fair market value of the shares of our common stock on the first business day or the last business day of the offering period, whichever is lower, provided that no more $25,000 worth of common stock (or such other lesser maximum number of shares as may be established by the administrator) may be purchased by any one employee during any

offering period. Under applicable tax rules, an employee may purchase no more than $25,000 worth of shares of our common stock, valued at the start of the purchase period, under the ESPP in any calendar year.

The accumulated payroll deductions of any employee who is not a participant on the last day of an offering period will be refunded. An employee's rights under the ESPP terminate upon voluntary withdrawal from the plan or when the employee ceases employment with us for any reason.

The ESPP may be terminated or amended by our board of directors at any time. An amendment that increases the number of shares of our common stock authorized under the ESPP and certain other amendments require the approval of our stockholders.

Senior Executive Cash Incentive Bonus Plan

On July 10, 2021, our board of directors adopted the Senior Executive Cash Incentive Bonus Plan, or the Bonus Plan. The Bonus Plan provides for annual cash bonus payments based upon the attainment of company and individual performance targets established by our compensation committee. The payment targets will be related to financial and operational measures or objectives with respect to our company, or the Corporate Performance Goals, as well as individual performance objectives.

Our compensation committee may select Corporate Performance Goals from among the following: cash flow (including, but not limited to, operating cash flow and free cash flow); revenue; corporate revenue; earnings before interest, taxes, depreciation and amortization; net income (loss) (either before or after interest, taxes, depreciation and/or amortization); changes in the market price of our common stock; economic value-added; development, clinical, regulatory or commercial milestones; acquisitions or strategic transactions, including collaborations, joint ventures or promotion arrangements; operating income (loss); return on capital assets, equity, or investment; stockholder returns; return on sales; gross or net profit levels; productivity; expense efficiency; margins; operating efficiency; customer satisfaction; working capital; earnings (loss) per share of our common stock; bookings, new bookings or renewals; sales or market shares; number of customers, number of new customers or customer references; operating income and/or net annual recurring revenue; or any other performance goal as selected by the compensation committee, any of which may be measured in absolute terms, as compared to any incremental increase, in terms of growth, as compared to results of a peer group, against the market as a whole, compared to applicable market indices and/or measured on a pre-tax or post-tax basis.

Each executive officer who is selected to participate in the Bonus Plan will have a target bonus opportunity set for each performance period. The bonus formulas will be adopted in each performance period by the compensation committee and communicated to each executive. The Corporate Performance Goals will be measured at the end of each performance period after our financial reports have been published or such other appropriate time as the compensation committee determines. If the Corporate Performance Goals and individual performance objectives are met, payments will be made as soon as practicable following the end of each performance period, but no later than 74 days after the end of the fiscal year in which such performance period ends. Subject to the rights contained in any agreement between the executive officer and us, an executive officer must be employed by us on the bonus payment date to be eligible to receive a bonus payment. The Bonus Plan also permits the compensation committee to approve additional bonuses to executive officers in its sole discretion.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Other than compensation arrangements, we describe below the transactions, and series of similar transactions, since January 1, 2018, to which we were a party or will be a party, in which:

- the amounts involved exceeded or will exceed $120,000; and
- any of our directors, executive officers or holders of more than 5% of our capital stock, or any member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest.

Prior to this offering, we did not have a formal policy concerning transactions with related persons. In connection with this offering, we plan to adopt a written policy, effective upon completion of this offering, that requires all future transactions between us and any director, executive officer, holder of 5% or more of any class of our capital stock or any member of the immediate family of, or entities affiliated with, any of them, or any other related persons (as defined in Item 404 of Regulation S-K) or their affiliates, in which the amount involved is equal to or greater than $120,000, be approved in advance by our audit committee. Any request for such a transaction must first be presented to our audit committee for review, consideration and approval. In approving or rejecting any such proposal, our audit committee is to consider the relevant facts and circumstances available and deemed relevant to the audit committee, including, but not limited to, the extent of the related party's interest in the transaction, and whether the transaction is on terms no less favorable to us than terms we could have generally obtained from an unaffiliated third party under the same or similar circumstances.

Private Placements of Securities

Series B Preferred Stock Financing

In November 2018, we issued and sold an aggregate of 11,155,406 shares of Series B preferred stock at a purchase price of $2.7696 per share. Certain investors holding convertible notes issued in 2016 used such notes to purchase our Series B preferred stock. Each share of our Series B preferred stock will convert automatically into one share of our common stock immediately prior to the completion of this offering. The following table summarizes purchases of our Series B preferred stock by related persons:

Name	SHARES OF SERIES B PREFERRED	AGGREGATE PURCHASE PRICE PAID
PBM ADV Holdings, LLC (1)	9,026,618	$ 25,000,121.21
Estuardo Aguilar-Cordova, M.D., Ph.D.	318,884	$ 883,181.13 (2)
Laura K. Aguilar, M.D., Ph.D.	58,246	$ 161,318.12 (3)
Estuardo Aguilar-Cordova, M.D., Ph.D., and Laura K. Aguilar, M.D., Ph.D.	79,635	$ 120,884.00 (4)
Fred Mermelstein (5)	19,909	$ 30,221.00 (6)

(1) PBM ADV Holdings, LLC is an affiliate of PBM Capital, and is the holder of five percent or more of our capital stock. Paul B. Manning is the Chairman and CEO of PBM Capital and is a member of our board of directors. PBM ADV Holdings, LLC transferred 696,851 of their Series B Preferred shares to GTAM1 2012 ADV LLC in December 2018. Chris Martell was formerly a Partner at PBM Capital, is the manager of GTAM1 2012 ADV LLC, and is a member of our board of directors. Diem Nguyen is the Chief Executive Officer of Xalud Therapeutics, Inc., which is majority-owned by PBM Capital.

(2) The aggregate purchase price was funded by the cancellation or conversion of indebtedness (including principal and interest) under a certain convertible promissory note, issued by us to Dr. Estuardo Aguilar-Cordova in January 2005.

(3) The aggregate purchase price was funded by the cancellation or conversion of indebtedness (including principal and interest) under a certain convertible promissory note, issued by us to Dr. Laura K. Aguilar in January 2005.

(4) The aggregate purchase price was funded by the cancellation or conversion of indebtedness (including principal and interest) under a certain convertible promissory note, issued by us to Dr. Aguilar-Cordova and Dr. Laura K. Aguilar in January 2005.

(5) Dr. Mermelstein resigned from our board of directors in November 2018.

(6) The aggregate purchase price was funded by the cancellation or conversion of indebtedness (including principal and interest) under certain convertible promissory notes, issued by us to Dr. Mermelstein in December 2015.

In connection with the Series B Preferred Stock Financing and the cancellation of the certain promissory notes held by Dr. Estuardo Aguilar-Cordova and Dr. Laura K. Aguilar, we also agreed to pay (i) Dr. Estuardo Aguilar-Cordova $354,230.33 on November 13, 2018 and $354,230.32 on November 13, 2019, and (ii) Dr. Laura K. Aguilar $168,168.85 on November 13, 2018 and $168,168.84 on November 13, 2019.

In connection with the Series B Preferred Stock Financing we also issued to PBM ADV Holdings, LLC two warrants to purchase, in the aggregate, up to 7,344,982 shares of our common stock. Subsequently, PBM ADV Holdings, LLC transferred their warrant to purchase 567,028 shares of our common stock to GTAM1 2012 ADV LLC in December 2018.

Series C Preferred Stock Financing

In March 2020, we issued and sold an aggregate of 6,032,170 shares of Series C preferred stock at a purchase price of $3.73 per share. Each share of our Series C preferred stock will convert automatically into one share of our common stock immediately prior to the completion of this offering. The following table summarizes purchases of our Series C preferred stock by related persons:

Name	SHARES OF SERIES C PREFERRED	AGGREGATE PURCHASE PRICE PAID
Northpond Ventures, LP	4,021,448	$ 15,000,000

(1) Northpond Ventures, LP is an affiliate of Northpond Ventures. Shaan Gandhi is a director at Northpond Ventures and a member of our board of directors.

Agreements with Stockholders

In connection with the Series C preferred stock financing, we entered into the Amended and Restated Investors' Rights Agreement, or the Investors' Rights Agreement, dated as of March 19, 2020, with certain of our stockholders, including our principal stockholders and their affiliates, the Amended and Restated Right of First Refusal and Co-Sale Agreement, dated as of March 19, 2020, with certain of our stockholders, including our principal stockholders and their affiliates, and the Amended and Restated Voting Agreement, dated as of March 19, 2020, with certain of our stockholders, including our principal stockholders and their affiliates. All of the material provisions of these agreements will terminate immediately prior to the completion of this offering, other than the provisions relating to registration rights, which will continue in effect following the completion of this offering and entitle the holders of such rights to have us register their shares of our common stock for sale in the U.S. See "Description of Capital Stock—Registration Rights."

Executive Officer and Director Compensation

See "Executive Compensation" for information regarding compensation of directors and executive officers.

Employment Agreements

We have entered into offer letters or employment agreements with each of our executive officers. For more information regarding our agreements with our named executive officers for the fiscal year ended December 31, 2020, see "Executive Compensation—Narrative to Summary Compensation Table—Employment Arrangements with Our Named Executive Officers."

Indemnification Agreements

We have entered into or plan to enter into indemnification agreements with each of our directors and executive officers, the form of which is attached as an exhibit to the registration statement of which this prospectus is a part. The indemnification agreements and our amended and restated certificate of incorporation and amended and restated bylaws require us to indemnify our directors and officers to the fullest extent permitted by Delaware law.

Lease Agreements

In January 2008, we entered into an operating lease agreement with a term through December 31, 2022 with Ellka, for the space in which we operated until we entered into a termination agreement, and the lease was terminated in February 2021. We also entered into a lease for a living space for employees in Auburndale, MA, which terminated in January 2021. In May 2016, we entered into a second lease agreement with Ellka for living space for employees, also in Auburndale, MA. We entered into a second lease for this space on July 26, 2018, which expired on July 31, 2019. Ellka was originally established in 2007 as an LLC for the purpose of acquiring and managing investment properties owned by Laura Aguilar and Estuardo Aguilar-Cordova and their children's trusts. Ellka is owned and operated by Laura Aguilar and Estuardo Aguilar-Cordova and members of their immediate family.

License Agreements

We entered into an exclusive license agreement with Ventagen LLC, or Ventagen, in March 2014, which granted Ventagen the right to develop, commercialize and distribute products in Mexico, Belize, Guatemala, Honduras, El Salvador, Costa Rica, Nicaragua, Panama, Columbia and Bolivia, in exchange for a $1 million upfront fee and potential future milestone payment of $2.5 million. Stockholders of the Company own 49.5% of the voting stock of Ventagen, including 47% by Estuardo Aguilar-Cordova and Laura Aguilar and trusts for the benefit of their children.

Directed Share Program

At our request, the underwriters have reserved up to 5% of the shares offered by this prospectus for sale at the initial public offering price in a directed share program for our directors, officers, employees and related persons. See “Underwriting” for additional information.

PRINCIPAL STOCKHOLDERS

The following table presents information concerning the beneficial ownership of the shares of our common stock as of June 30, 2021, by:

- each person we know to be the beneficial owner of 5% or more of our outstanding shares of our capital stock;
- each of our directors;
- each of our named executive officers; and
- all of our executive officers and directors as a group.

We have determined beneficial ownership in accordance with SEC rules. The information does not necessarily indicate beneficial ownership for any other purpose. Under these rules, a person is deemed to be a beneficial owner of our common stock if that person has a right to acquire ownership within 60 days by the exercise of options or the conversion of our redeemable convertible preferred stock. A person is also deemed to be a beneficial owner of our common stock if that person has or shares voting power, which includes the power to vote or direct the voting of our common stock, or investment power, which includes the power to dispose of or to direct the disposition of such capital stock. Except in cases where community property laws apply or as indicated in the footnotes to this table, we believe that each stockholder identified in the table possesses sole voting and investment power over all shares of common stock shown as beneficially owned by the stockholder.

The percentage of beneficial ownership prior to this offering in the table below is based on 18,798,454 shares of common stock deemed to be outstanding as of June 30, 2021, assuming the conversion of all outstanding shares of redeemable convertible preferred stock into an aggregate of 7,066,565 shares of common stock immediately prior to the completion of this offering, and the percentage of beneficial ownership after this offering in the table below is based on 27,798,454 shares of common stock assumed to be outstanding after the completion of this offering. The table below assumes that the underwriters do not exercise their option to purchase additional shares. If the underwriters exercise their option to purchase additional shares in full, we will sell an aggregate of 10,350,000 additional shares of common stock. Shares of common stock subject to options that are currently exercisable or exercisable within 60 days of June 30, 2021 are considered outstanding and beneficially owned by the person holding the options for the purpose of computing the percentage ownership of that person but are not treated as outstanding for the purpose of computing the percentage ownership of any other person. The percentages of shares beneficially owned after this offering set forth below are calculated without giving effect to any potential purchases in this offering, including pursuant to the directed share program relating to this offering. Unless otherwise indicated below, the address of each individual listed below is c/o Candel Therapeutics, Inc., 117 Kendrick St, Suite 450, Needham, Massachusetts 02494.

Name and Address of Beneficial Owner	NUMBER OF SHARES BENEFICIALLY OWNED BEFORE OFFERING	PERCENTAGE OF SHARES BENEFICIALLY OWNED BEFORE OFFERING	PERCENTAGE OF SHARES BENEFICIALLY OWNED AFTER OFFERING
5% or Greater Stockholders:			
Entities affiliated with PBM Capital (1)	6,777,954	30.5%	21.7%
Northpond Ventures, LP (2)	1,685,326	9.0%	6.1%
EAC Descendants Irrevocable Trust (3)	942,338	5.0%	3.4%
LKA Descendants Irrevocable Trust (4)	942,338	5.0%	3.4%
Named Executive Officers and Directors:			
Paul Peter Tak, M.D, Ph.D. FMedSci (5).	444,217	2.3%	1.6%
Estuardo Aguilar-Cordova, M.D., Ph.D. (6)..	3,138,377	16.7%	11.3%
Laura K. Aguilar, M.D., Ph.D. (7).	2,995,923	15.9%	10.8%
John Canepa	*	*	*
Carrie S. Cox (8)	7,910	*	*
Edward J. Benz, Jr., M.D. (9)	60,010	*	*

Name and Address of Beneficial Owner	NUMBER OF SHARES BENEFICIALLY OWNED BEFORE OFFERING	PERCENTAGE OF SHARES BENEFICIALLY OWNED BEFORE OFFERING	PERCENTAGE OF SHARES BENEFICIALLY OWNED AFTER OFFERING
Shaan C. Gandhi, M.D., D.Phil	—	*	*
Paul B. Manning (10)	6,777,954	30.5%	21.7%
Udi Meirav, Ph.D. (11)	161,722	*	*
Alan E. Smith, Ph.D., FRS, CBE (12)	68,147	*	*
Chris Martell (13)	599,576	3.1%	2.1%
All executive officers and directors as a group (thirteen persons) (14)	14,253,836	70.1%	48.5%

* Represents beneficial ownership of less than one percent.

(1) Consists of (i) 3,388,977 shares of common stock issuable upon conversion of our Series B Preferred Stock held by PBM ADV Holdings, LLC and (ii) 3,388,977 shares of common stock issuable upon the exercise of warrants held by PBM ADV Holdings, LLC. In July 2021, PBM ADV Holdings, LLC distributed all of the shares of Series B convertible preferred stock it then held and its interest in the November 2018 warrants to its beneficial owners, including the distribution of 2,755,731 shares of Series B Preferred Stock and warrants to purchase 2,755,731 shares of our Common Stock to Paul B. Manning and entities controlled by Mr. Manning for no additional consideration in accordance with the terms of its operating agreement. Under the terms of the distribution, Mr. Manning retains sole voting and shared dispositive power over such distributed securities through the completion of this offering, at which time Mr. Manning's voting and dispositive power over the distributed shares will terminate except with respect to any shares held by Mr. Manning or by entities controlled by Mr. Manning. PBM ADV Holdings, LLC is majority owned by PBM Capital Investments II, LLC, and is managed by PBM Capital. Paul B. Manning, a member of our board of directors, is the Chief Executive Officer of PBM Capital and has sole voting and investment power with respect to the shares held by PBM ADV Holdings, LLC. The business address for each person and entity named in this footnote is 200 Garrett Street, Suite S, Charlottesville, Virginia 22902.

(2) Consists of 1,685,768 shares of our common stock issuable upon conversion of our Series C Preferred Stock held by Northpond Ventures, LP ("Northpond"). Northpond LP is managed by Northpond Ventures GP, LLC ("Northpond LLC") and Northpond LLC may be deemed to beneficially own such shares. Michael Rubin is the managing member of Northpond LLC and may also be deemed to beneficially own such shares. The business address for each person and entity named in this footnote is 7500 Old Georgetown Rd, Suite 850, Bethesda, MD 20814.

(3) Consists of 942,338 shares of common stock. Stephen Scherer and Katherine Michelle Rives, as trustees, have voting and dispositive power over the shares.

(4) Consists of 942,338 shares of common stock. Stephen Scherer and Katherine Michelle Rives, as trustees, have voting and dispositive power over the shares.

(5) Consists of 444,217 shares of common stock issuable upon the exercise of options exercisable within 60 days after June 30, 2021.

(6) Consists of (i) 853,786 shares of common stock, (ii) 129,738 shares of Series B Preferred Stock held solely by Dr. Aguilar-Cordova, (iii) 32,399 shares of Series B Preferred Stock held jointly with his spouse, Laura K. Aguilar, M.D., Ph.D., (iv) 2,074,942 shares held for the benefit of Dr. Aguilar-Cordova by the Estuardo Aguilar-Cordova 2020 Irrevocable Trust and (v) 47,512 shares of common stock issuable upon the exercise of options exercisable within 60 days after June 30, 2021.

(7) Consists of (i) 874,943 shares of common stock, (ii) 23,697 shares of Series B Preferred Stock held solely by Dr. Aguilar, (iii) 32,399 shares of Series B Preferred Stock held jointly with her spouse, Estuardo Aguilar-Cordova, M.D., Ph.D., (iv) 2,013,100 shares held for the benefit of Dr. Aguilar by the Laura K. Aguilar 2020 Irrevocable Trust and (v) 51,784 shares of common stock issuable upon the exercise of options exercisable within 60 days after June 30, 2021.

(8) Consists of 7,910 shares of common stock issuable upon the exercise of options exercisable within 60 days after June 30, 2021.

(9) Consists of 60,010 shares of common stock issuable upon the exercise of options exercisable within 60 days after June 30, 2021.

(10) Paul B. Manning does not hold any shares of our common stock in his capacity as director. Paul B. Manning is the Chairman and CEO of PBM Capital and is a member of our board of directors. PBM Capital is an affiliate of PBM ADV Holdings, LLC, a holder of five percent or more of our capital stock.

(11) Consists of (i) 48,822 shares of common stock and (ii) 112,900 shares of common stock issuable upon the exercise of options exercisable within 60 days after June 30, 2021.

(12) Consists of (i) 32,548 shares of common stock and (ii) 35,599 shares of common stock issuable upon the exercise of options exercisable within 60 days after June 30, 2021.

(13) Consists of (i) 32,548 shares of common stock issuable upon the exercise of options exercisable within 60 days after (ii) 283,514 shares of Series B Preferred Stock held by GTAM1 2012 ADV LLC, of which Mr. Martell serves as Manager, and (iii) 283,514 warrants held by GTAM1 2012 Trust, of which Mr. Martell serves as trustee but is not a beneficiary. Mr. Martell disclaims beneficial ownership over all of these interests, except for his beneficial ownership in the 32,548 shares of common stock issuable upon the exercise of options exercisable within 60 days after June 30, 2021.

(14) See footnotes 5 to 13. Also includes shares beneficially owned by Nathan Caffo and Susan Stewart, J.D., each of whom are executive officers but not named executive officers.

DESCRIPTION OF CAPITAL STOCK

Upon the completion of this offering and after giving effect to the conversion into common stock and retirement of all outstanding shares of our redeemable convertible preferred stock, our authorized capital stock will consist of 150,000,000 shares of common stock, par value $0.01 per share, and 10,000,000 shares of preferred stock, par value $0.01 per share, all of which will be undesignated, and there will be 27,798,454 shares of common stock outstanding and no shares of preferred stock outstanding. As of March 31, 2021, we had approximately 350 record holders of our capital stock. All of our outstanding shares of redeemable convertible preferred stock will convert into shares of our common stock upon the completion of this offering. In addition, upon the completion of this offering, options to purchase shares of our common stock will be outstanding and 2,347,000 shares of our common stock will be reserved for future grants under our equity incentive plans.

The following description of our capital stock and provisions of our amended and restated certificate of incorporation and amended and restated bylaws are summaries of material terms and provisions and are qualified by reference to our amended and restated certificate of incorporation and amended and restated bylaws, copies of which have been filed with the SEC as exhibits to the registration statement of which this prospectus is a part. The descriptions of our common stock and preferred stock reflect amendments to our amended and restated certificate of incorporation and amended and restated bylaws that will become effective upon the completion of this offering.

Common Stock

Upon the completion of this offering, we will be authorized to issue one class of common stock. Holders of our common stock are entitled to one vote for each share of common stock held of record for the election of directors and on all matters submitted to a vote of stockholders. Holders of our common stock are entitled to receive dividends ratably, if any, as may be declared by our board of directors out of legally available funds, subject to any preferential dividend rights of any preferred stock then outstanding. The holders of our common stock do not have any cumulative voting rights. Upon our dissolution, liquidation or winding up, holders of our common stock are entitled to share ratably in our net assets legally available after the payment of all our debts and other liabilities, subject to the preferential rights of any preferred stock then outstanding. Holders of our common stock have no preemptive, subscription, redemption or conversion rights and no sinking fund provisions are applicable to our common stock. The rights, preferences and privileges of holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future. Except as described under “Antitakeover Effects of Delaware Law and Provisions of our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws” below, a majority vote of the holders of common stock is generally required to take action under our amended and restated certificate of incorporation and amended and restated bylaws.

Preferred Stock

Upon the completion of this offering, our board of directors will be authorized, without action by the stockholders, to designate and issue up to an aggregate of 10,000,000 shares of preferred stock in one or more series. Our board of directors can designate the rights, preferences and privileges of the shares of each series and any of its qualifications, limitations or restrictions. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of common stock. The issuance of preferred stock, while providing flexibility in connection with possible future financings and acquisitions and other corporate purposes could, under certain circumstances, have the effect of restricting dividends on our common stock, diluting the voting power of our common stock, impairing the liquidation rights of our common stock, or delaying, deferring or preventing a change in control of our company, which might harm the market price of our common stock. See also “Antitakeover Effects of Delaware Law and Provisions of our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws—Provisions of our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws—Undesignated preferred stock” below.

Our board of directors will make any determination to issue such shares based on its judgment as to our company’s best interests and the best interests of our stockholders. Upon the completion of this offering, we will have no shares of preferred stock outstanding and we have no current plans to issue any shares of preferred stock following completion of this offering.

Warrants

In connection with the November 13, 2018 issuance of Series B Preferred Stock, we issued warrants to purchase 3,672,491 shares of common stock for $6.81 per share to a purchaser of our Series B Preferred Stock which were immediately and fully exercisable upon issuance, or the Unconditional Series B Warrants. We also issued warrants for the purchase of up to an additional 3,672,491 shares of common for $6.81 per share, or the Conditional Series B Warrants. As amended on July 14, 2014, each of the Unconditional Series B Warrants and Conditional Series B Warrants expire in November 2025.

The Conditional Series B Warrants are only exercisable in the event that we achieve certain financial conditions as follows: 918,123 shares vest upon a financing event effected through the sale of our equity securities to third parties resulting in at least $20,000,000 in gross proceeds, or a Financing Event, with a price per share of, or average market price (determined over a consecutive 10-day period) of, $12.47 per share; an additional 918,123 shares vest upon a Financing Event with a price per share of, or average market price of, $13.20 per share; an additional 918,122 shares vest upon a Financing Event with a price per share of, or average market price of, $13.94 per share; and an additional 918,122 shares vest upon a Financing Event with a price per share of, or average market price of, $14.68 per share. Based on the initial public offering price of $8.00 per share, the consummation of our initial public offering will not be a Financing Event that will result in the vesting of the Conditional Series B Warrants.

The Unconditional Series B Warrants contain provisions allowing for cash and on a cashless exercise basis. The Conditional Series B Warrants are only exercisable in connection with the first to occur of (i) a sale of the Company or (ii) the Conditional Series B Warrants' expiration in November 2025. The Conditional Series B Warrants contain provisions allowing for cash and on a cashless exercise basis in connection with a sale event, and only on a cashless exercise basis in connection with the Conditional Series B Warrants' expiration in November 2025.

As of March 31, 2021, PBM ADV Holdings, LLC and GTAM1 2012 LLC owned all of the Unconditional Series B Warrants and the Conditional Series B Warrants. PBM ADV Holdings, LLC holds warrants to purchase, in the aggregate, 6,777,954 shares of our common stock. Such warrants, if fully exercised for cash in connection with this offering, would result in PBM ADV Holdings, LLC beneficially owning 33.4% of our common stock. Paul B. Manning, a member of our board of directors, is affiliated with PBM ADV Holdings, LLC. In addition, GTAM1 2012 LLC holds warrants to purchase, in the aggregate, 567,028 shares of our common stock. Such warrants, if fully exercised for cash in connection with this offering, would result in GTAM1 2012 LLC beneficially owning 2.8% of our common stock. Chris Martell, a member of our board of directors, is affiliated with GTAM1 2012 ADV LLC.

Registration Rights

Upon the completion of this offering, the holders of 8,884,661 shares of our common stock, including shares issuable upon the conversion of our convertible preferred stock, or their permitted transferees, which we refer to as our registrable securities, are entitled to rights with respect to the registration of these securities under the Securities Act. These rights are provided under the terms of the Investors' Rights Agreement. The Investors' Rights Agreement includes demand registration rights, short-form registration rights and piggyback registration rights. All fees, costs and expenses incurred in connection with registrations under the Investors' Rights Agreement will be borne by us, and all selling expenses, including underwriting discounts and selling commissions, will be borne by the holders of the shares being registered.

Demand Registration Rights

Upon the completion of this offering, the holders of our registrable securities are entitled to demand registration rights. Under the terms of the investor rights agreement, we will be required, upon the request of holders of at least 25% of our outstanding registrable securities, to file a registration statement with an anticipated offering amount of at least $3.0 million and use commercially reasonable efforts to effect the registration of these shares for public resale. We are required to effect up to two registrations pursuant to this provision of the Investors' Rights Agreement. A demand for registration may not be made until six months after the effective date of the registration statement for this offering.

Short Form Registration Rights

Upon the completion of this offering, the holders of our registrable securities are also entitled to short form registration rights. Pursuant to the Investors' Rights Agreement, if we are eligible to file a registration statement on Form S-3, upon the request of holders of at least 10% of our outstanding registrable securities to sell registrable securities with an anticipated aggregate offering amount of at least $1.0 million, we will be required to use our commercially reasonable efforts to effect a registration of such shares. We are required to effect up to two registrations in any twelve month period pursuant to this provision of the Investors' Rights Agreement.

Piggyback Registration Rights

The holders of our registrable securities are entitled to piggyback registration rights. If we register any of our securities either for our own account or for the account of other security holders, the holders of our outstanding registrable securities are entitled to include their shares in the registration. Subject to certain exceptions contained in the Investors' Rights Agreement, we and the underwriters may limit the number of shares included in the underwritten offering if the underwriters determine that marketing factors require a limitation of the number of shares to be underwritten.

Indemnification

Our Investors' Rights Agreement contains customary cross-indemnification provisions, under which we are obligated to indemnify holders of registrable securities in the event of material misstatements or omissions in the registration statement attributable to us, and they are obligated to indemnify us for material misstatements or omissions attributable to them.

Expiration of Registration Rights

The registration rights granted under the investor rights agreement will terminate upon the earlier of (i) a deemed liquidation event, as defined in our amended and restated certificate of incorporation (as in effect prior to the completion of this offering) or certain other events constituting a sale of the company, (ii) at such time after our initial public offering when all registrable securities could be sold under Rule 144 of the Securities Act or a similar exemption without limitation during a three-month period without registration or (iii) the fifth anniversary of our initial public offering.

Antitakeover Effects of Delaware Law and Provisions of our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Certain provisions of the Delaware General Corporation Law and of our amended and restated certificate of incorporation and amended and restated bylaws that will become effective upon the completion of this offering could have the effect of delaying, deferring or discouraging another party from acquiring control of us. These provisions, which are summarized below, are expected to discourage certain types of coercive takeover practices and inadequate takeover bids and, as a consequence, they might also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions are also designed in part to encourage anyone seeking to acquire control of us to first negotiate with our board of directors. These provisions might also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders might otherwise deem to be in their best interests. However, we believe that the advantages gained by protecting our ability to negotiate with any unsolicited and potentially unfriendly acquirer outweigh the disadvantages of discouraging such proposals, including those priced above the then-current market value of our common stock, because, among other reasons, the negotiation of such proposals could improve their terms.

Delaware Anti-Takeover Statute

Upon completion of this offering, we will be subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or
- at or after the time the stockholder became interested, the business combination was approved by our board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, lease, pledge, exchange, mortgage or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Provisions of our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Our amended and restated certificate of incorporation and amended and restated bylaws to be in effect upon completion of this offering will include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

Board composition and filling vacancies. Our amended and restated certificate of incorporation provides for the division of our board of directors into three classes serving staggered three-year terms, with one class being elected each year. Our amended and restated certificate of incorporation also provides that directors may be removed only for cause and then only by the affirmative vote of the holders of two-thirds or more of the shares then entitled to vote at an election of directors. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum. The classification of directors, together with the limitations on removal of directors and treatment of vacancies, has the effect of making it more difficult for stockholders to change the composition of our board of directors.

No written consent of stockholders. Our amended and restated certificate of incorporation provides that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the amendment of our bylaws or removal of directors by our stockholders without holding a meeting of stockholders.

Meetings of stockholders. Our certificate of incorporation and bylaws provide that only a majority of the members of our board of directors then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance notice requirements. Our bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must

be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our bylaws specify the requirements as to form and content of all stockholders' notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

Amendment to certificate of incorporation and bylaws. Any amendment of our amended and restated certificate of incorporation must first be approved by a majority of our board of directors, and if required by law or our amended and restated certificate of incorporation, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment, and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of the provisions relating to stockholder action, board composition, and limitation of liability must be approved by not less than two-thirds of the outstanding shares entitled to vote on the amendment, and not less than two-thirds of the outstanding shares of each class entitled to vote thereon as a class. Our bylaws may be amended by the affirmative vote of a majority vote of the directors then in office, subject to any limitations set forth in the bylaws; and may also be amended by the affirmative vote of not less than two-thirds of the outstanding shares entitled to vote on the amendment, or, if the board of directors recommends that the stockholders approve the amendment, by the affirmative vote of the majority of the outstanding shares entitled to vote on the amendment, in each case voting together as a single class.

Undesignated preferred stock. Upon the completion of this offering, our amended and restated certificate of incorporation will provide for authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our board of directors to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our amended and restated certificate of incorporation grants our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Choice of Forum

Our by-laws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Chancery Court does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) will be the sole and exclusive forum for: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders; (3) any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our certificate of incorporation or by-laws (including the interpretation, validity or enforceability thereof) or (4) any action asserting a claim governed by the internal affairs doctrine. Our by-laws of incorporation also provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to this choice of forum provision. It is possible that a court of law could rule that the choice of forum provision contained in our restated certificate of incorporation is inapplicable or unenforceable if it is challenged in a proceeding or otherwise.

In addition, our by-laws provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States will be the exclusive forum for any private action asserting violations by us or any of our directors or officers of the Securities Act or the Exchange Act, or the rules and regulations promulgated thereunder, and of all suits in equity and actions at law brought to enforce any liability or duty created by those statutes or the rules and regulations under such statutes. If any action the subject matter of which is within the scope of the preceding sentence is filed in a court other than the federal district courts of the United States, the plaintiff or plaintiffs shall be deemed by this provision of the bylaws (i) to have consented to removal of the action by us to the federal district courts of the United States, in the case of an action filed in a state court, and (ii) to have consented to transfer of the action to the federal district courts of the United States

We recognize that the Delaware Forum Provision in our bylaws may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware. Additionally, the forum selection clauses in our amended and restated bylaws may limit our stockholders' ability to bring a claim in a forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court were "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the federal district courts of the United States may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC. The transfer agent and registrar's address is 6201 15th Avenue, Brooklyn, NY 11219, and its telephone number is (718) 921-8200.

Listing

We have applied to list our common stock on The Nasdaq Global Market under the symbol "CADL."

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock. Future sales of our common stock in the public market, or the availability of such shares for sale in the public market, could adversely affect market prices prevailing from time to time. As described below, only a limited number of shares will be available for sale shortly after this offering due to contractual and legal restrictions on resale. Nevertheless, sales of our common stock in the public market after such restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price at such time and our ability to raise equity capital in the future.

Based on the number of shares of common stock outstanding as of June 30, 2021, upon the completion of this offering, 27,798,454 shares of our common stock will be outstanding, assuming no exercise of the underwriters' option to purchase additional shares and no exercise of outstanding options. Of the outstanding shares, all of the shares sold in this offering will be freely tradable, except that any shares held by our affiliates, as that term is defined in Rule 144 under the Securities Act, may only be sold in compliance with the limitations described below, and shares of our common stock are restricted shares of common stock subject to time-based vesting terms.

Rule 144

In general, a person who has beneficially owned restricted stock for at least six months would be entitled to sell their securities provided that (i) such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale and (ii) we are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Persons who have beneficially owned restricted shares for at least six months but who are our affiliates at the time of, or any time during the 90 days preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of either of the following:

- 1% of the number of shares then outstanding, which will equal approximately 278,000 shares immediately after this offering assuming no exercise of the underwriters' option to purchase additional shares, based on the number of shares outstanding as of March 31, 2021; or
- the average weekly trading volume of our common stock on The Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale;

provided, in each case, that are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Such sales both by affiliates and by non-affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144.

Rule 701

Rule 701 under the Securities Act, as in effect on the date of this prospectus, permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Most of our employees, executive officers or directors who purchased shares under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the effectiveness of the registration statement of which this prospectus forms a part before selling their shares. However, substantially all Rule 701 shares are subject to lock-up agreements as described below and under "Underwriting" included elsewhere in this prospectus and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

Lock-up Agreements

In connection with this offering, we, each of our directors and executive officers, and holders of substantially all of the shares of our outstanding stock have agreed with the underwriters that for a period of 180 days following the date of this prospectus, subject to certain exceptions, we will not offer, sell, assign, transfer, pledge, contract to sell or otherwise dispose of or hedge any shares of our common stock or any securities convertible into or exchangeable for shares of our common stock. The underwriters may, in their sole discretion, at any time, release all or any portion of the shares from the restrictions in this agreement.

Rule 10b5-1 Trading Plans

Following the completion of this offering, certain of our officers, directors and other employees may adopt written plans, known as Rule 10b5-1 trading plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis to diversify their assets and investments. Under these 10b5-1 trading plans, a broker may execute trades pursuant to parameters established by the officer or director when entering into the plan, without further direction from such officer or director. Such sales would not commence until the expiration of the applicable lock-up agreements entered into by such officer or director in connection with this offering.

Registration Rights

Upon completion of this offering, certain holders of our securities will be entitled to various rights with respect to registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration statement. See the section entitled “Description of Capital Stock—Registration rights” appearing elsewhere in this prospectus for more information.

Equity Incentive Plans

We intend to file one or more registration statements on Form S-8 under the Securities Act to register our shares issued or reserved for issuance under our equity incentive plans. The first such registration statement is expected to be filed soon after the date of this prospectus and will automatically become effective upon filing with the SEC. Accordingly, shares registered under such registration statement will be available for sale in the open market, unless such shares are subject to vesting restrictions with us or the lock-up restrictions described above.

Warrants

The 7,344,982 shares of common stock issuable under the Unconditional Series B Warrants and Conditional Series B Warrants may be available for sale in the open market once issued, subject to resale restrictions under Rule 144 for certain affiliates of ours that may hold such warrants at the time of such exercise.

MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS OF COMMON STOCK

The following discussion is a summary of material U.S. federal income tax considerations applicable to non-U.S. holders (as defined below) with respect to their ownership and disposition of shares of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. For purposes of this discussion, a non-U.S. holder means a beneficial owner of our common stock that is for U.S. federal income tax purposes:

- a non-resident alien individual;
- a corporation or any other organization taxable as a corporation for U.S. federal income tax purposes that is created or organized in or under laws other than the laws of the United States, any state thereof, or the District of Columbia;
- an estate the income of which is not subject to U.S. federal income tax on a net income basis; or
- a trust (1) that (a) has not made an election to be treated as a U.S. person under applicable U.S. Treasury regulations and (b) either (i) is not subject to the primary supervision of a court within the United States or (ii) is not subject to the substantial control of one or more U.S. persons or (2) the income of which is not subject to U.S. federal income tax on a net income basis.

This discussion does not address the tax treatment of partnerships or other entities or arrangements that are treated as pass-through entities for U.S. federal income tax purposes or persons that hold their shares of common stock through partnerships or such other pass-through entities. The tax treatment of a partner in a partnership or other entity or arrangement that is treated as a pass-through entity for U.S. federal income tax purposes generally will depend upon the status of the partner and the activities of the partnership. A partner in a partnership or an investor in any other pass-through entity that will hold our common stock should consult his, her or its tax advisor regarding the tax consequences of acquiring, holding and disposing of our common stock through a partnership or other pass-through entity, as applicable.

This discussion is based on current provisions of the Internal Revenue Code of 1986, as amended, or the Code, existing and proposed U.S. Treasury regulations promulgated thereunder, current administrative rulings and judicial decisions, all as in effect as of the date of this prospectus and, all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any such change or differing interpretation could alter the tax consequences to non-U.S. holders described in this prospectus. We have not sought and will not seek any rulings from the Internal Revenue Service, or the IRS, regarding the matters discussed below. There can be no assurance that the IRS, will not challenge one or more of the tax consequences described herein. We assume in this discussion that a non-U.S. holder holds shares of our common stock as a “capital asset” within the meaning of Section 1221 of the Code, which is generally property held for investment.

This discussion does not address all aspects of U.S. federal income taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder’s individual circumstances nor does it address any aspects of any U.S. federal tax other than the income tax, U.S. state, local or non-U.S. taxes, the alternative minimum tax, or the Medicare tax on net investment income. This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder and does not address the special tax rules applicable to particular non-U.S. holders, such as:

- insurance companies;
- tax-exempt or governmental organizations;
- financial institutions;
- brokers or dealers in securities;
- regulated investment companies;
- pension plans;
- “controlled foreign corporations,” “passive foreign investment companies,” and corporations that accumulate earnings to avoid U.S. federal income tax;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;

- persons that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment;
- persons that hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation; and
- certain U.S. expatriates.

This discussion is for general information only and is not tax advice. Accordingly, all prospective non-U.S. holders of our common stock should consult their tax advisors with respect to the U.S. federal, state, local, estate and non-U.S. tax consequences of the purchase, ownership and disposition of our common stock.

Distributions on Our Common Stock

As described in the "Dividend Policy" section above, we do not intend to pay any dividends in cash or property on our common stock in the foreseeable future. Distributions of cash or property, if any, on shares of our common stock generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a return of the non-U.S. holder's investment, up to such holder's adjusted tax basis in the shares of common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below in "Gain on Sale or Other Taxable Disposition of Our Common Stock." Any such distributions will also be subject to the discussion below under the section titled "Withholding and Information Reporting Requirements—FATCA."

Subject to the discussion in the following two paragraphs in this section, dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends or such lower rate specified by an applicable income tax treaty between the United States and such holder's country of residence.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the United States, are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements. However, such U.S. effectively connected income, net of specified deductions and credits, is taxed at the same U.S. federal income tax rates applicable to United States persons (as defined in the Code). Any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also, under certain circumstances, be subject to an additional "branch profits tax" at a 30% rate or such lower rate as specified by an applicable income tax treaty between the United States and such holder's country of residence.

A non-U.S. holder of shares of our common stock who claims the benefit of an applicable income tax treaty between the United States and such holder's country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E (or a successor form) to the applicable withholding agent and satisfy applicable certification and other requirements. Non-U.S. holders are urged to consult their tax advisors regarding their entitlement to benefits under a relevant income tax treaty. A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may generally obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim with the IRS.

Gain on Sale or Other Taxable Disposition of Our Common Stock

Subject to the discussion below under "Withholding and Information Reporting Requirements—FATCA," a non-U.S. holder generally will not be subject to any U.S. federal income tax on any gain recognized upon such holder's sale, exchange or other taxable disposition of shares of our common stock unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a U.S. trade or business and, if an applicable income tax treaty so provides, is attributable to a permanent establishment or a fixed-base maintained by such non-U.S. holder in the United States, in which case the non-U.S. holder generally will be taxed on a net income basis at the same U.S. federal income tax rates applicable to United States persons (as defined in the Code) and, if the non-U.S. holder is a foreign corporation, the branch profits tax described above in "Distributions on Our Common Stock" also may apply;

- the non-U.S. holder is a nonresident alien individual who is present in the United States for a period or periods aggregating 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence) on the net gain derived from the disposition, which may be offset by certain U.S. source capital losses of the non-U.S. holder, if any (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses; or
- we are, or have been, at any time during the five-year period preceding such sale or other taxable disposition (or the non-U.S. holder's holding period, if shorter) a "U.S. real property holding corporation," unless our common stock is regularly traded on an established securities market, within the meaning of the relevant provisions of the Code, and the non-U.S. holder holds no more than 5% of our outstanding common stock, directly or indirectly, actually or constructively, during the shorter of the five-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. If we are determined to be a U.S. real property holding corporation and the foregoing exception does not apply, then the non-U.S. holder generally will be taxed on its net gain derived from the sale or other taxable disposition at the U.S. federal income tax rates applicable to United States persons (as defined in the Code). Generally, a corporation is a "U.S. real property holding corporation" only if the fair market value of its "U.S. real property interests" (as defined in the Code and applicable U.S. Treasury regulations) equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we do not believe that we are, or have been, a "U.S. real property holding corporation" for U.S. federal income tax purposes, or that we are likely to become one in the future. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above.

Backup Withholding and Information Reporting

We must report annually to the IRS and to each non-U.S. holder the gross amount of the distributions on shares of our common stock paid to such holder and the tax withheld, if any, with respect to such distributions. Non-U.S. holders may have to comply with specific certification procedures to establish that the holder is not a United States person (as defined in the Code) in order to avoid backup withholding at the applicable rate with respect to dividends on shares of our common stock. Generally, a non-U.S. holder will comply with such procedures if it provides a properly executed IRS Form W-8BEN or W-8BEN-E (or other applicable IRS Form W-8), or otherwise meets documentary evidence requirements for establishing that it is a non-U.S. holder, or otherwise establishes an exemption. Dividends paid to non-U.S. holders subject to withholding of U.S. federal income tax, as described above in "Distributions on Our Common Stock," generally will be exempt from U.S. backup withholding.

Information reporting and backup withholding will generally apply to the proceeds of a disposition of shares of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or non-U.S., unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. holders should consult their tax advisors regarding the application of the information reporting and backup withholding rules to them. Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement. Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be refunded or credited against the non-U.S. holder's U.S. federal income tax liability, if any, provided that an appropriate claim is filed with the IRS in a timely manner.

Withholding and Information Reporting Requirements—FATCA

The Foreign Account Tax Compliance Act, or FATCA, generally imposes a U.S. federal withholding tax at a rate of 30% on payments of dividends on our common stock paid to a foreign entity unless (i) if the foreign entity is a

“foreign financial institution,” such foreign entity undertakes certain due diligence, reporting, withholding, and certification obligations, (ii) if the foreign entity is not a “foreign financial institution,” such foreign entity identifies certain of its U.S. investors, if any, or (iii) the foreign entity is otherwise excepted under FATCA. Such withholding may also apply to payments of gross proceeds of sales or other dispositions of shares of our common stock, although under proposed U.S. Treasury regulations (the preamble to which specifies that taxpayers, including withholding agents, are generally permitted to rely on them pending finalization), no withholding will apply to payments of gross proceeds. If withholding under FATCA is required on any payment related to our common stock, under certain circumstances, a non-U.S. holder may be eligible for refunds or credits of this withholding tax. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph. Non-U.S. holders should consult their tax advisors regarding the possible implications of this legislation on their investment in our common stock and the entities through which they hold our shares of common stock, including, without limitation, the process and deadlines for meeting the applicable requirements to prevent the imposition of the 30% withholding tax under FATCA.

UNDERWRITING

Subject to the terms and conditions set forth in the underwriting agreement, dated July 26, 2021, among us and Jefferies LLC, Credit Suisse Securities (USA) LLC, BMO Capital Markets Corp. and UBS Securities LLC, as the representatives of the underwriters in this offering named below, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the respective number of shares of common stock shown opposite its name below:

UNDERWRITER	NUMBER OF SHARES
Jefferies LLC	3,600,000
Credit Suisse Securities (USA) LLC	2,430,000
BMO Capital Markets Corp.	1,800,000
UBS Securities LLC	1,170,000
Total	9,000,000

The underwriting agreement provides that the obligations of the several underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers' certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that the underwriters will purchase all of the shares of common stock if any of them are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated. We have agreed to indemnify the underwriters and certain of their controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make in respect of those liabilities.

The underwriters have advised us that, following the completion of this offering, they currently intend to make a market in the common stock as permitted by applicable laws and regulations. However, the underwriters are not obligated to do so, and the underwriters may discontinue any market-making activities at any time without notice in their sole discretion. Accordingly, no assurance can be given as to the liquidity of the trading market for the common stock, that you will be able to sell any of the common stock held by you at a particular time or that the prices that you receive when you sell will be favorable.

The underwriters are offering the shares of common stock subject to their acceptance of the shares of common stock from us and subject to prior sale. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part. In addition, the underwriters have advised us that they do not intend to confirm sales to any account over which they exercise discretionary authority.

Commission and Expenses

The underwriters have advised us that they propose to offer the shares of common stock to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers, which may include the underwriters, at that price less a concession not in excess of $0.336 per share of common stock. After the offering, the initial public offering price, concession and reallowance to dealers may be reduced by the representatives. No such reduction will change the amount of proceeds to be received by us as set forth on the cover page of this prospectus.

The following table shows the public offering price, the underwriting discounts and commissions that we are to pay the underwriters and the proceeds, before expenses, to us in connection with this offering. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	PER SHARE		TOTAL	
	WITHOUT OPTION TO PURCHASE ADDITIONAL SHARES	WITH OPTION TO PURCHASE ADDITIONAL SHARES	WITHOUT OPTION TO PURCHASE ADDITIONAL SHARES	WITH OPTION TO PURCHASE ADDITIONAL SHARES
Public offering price	$ 8.00	$ 8.00	$72,000,000	$82,800,000
Underwriting discounts and commissions paid by us	$ 0.56	$ 0.56	$ 5,040,000	$ 5,796,000
Proceeds to us, before expenses	$ 7.44	$ 7.44	$66,960,000	$77,004,000

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately $3,800,000. We have also agreed to pay the filing fees incident to, and the fees and disbursements of counsel for the underwriters in connection with, the required review by the Financial Industry Regulatory Authority, Inc. in an amount up to $40,000.

Determination of Offering Price

Prior to this offering, there has not been a public market for our common stock. Consequently, the initial public offering price for our common stock will be determined by negotiations between us and the representatives. Among the factors to be considered in these negotiations will be prevailing market conditions, our financial information, market valuations of other companies that we and the underwriters believe to be comparable to us, estimates of our business potential, the present state of our development and other factors deemed relevant.

We offer no assurances that the initial public offering price will correspond to the price at which the common stock will trade in the public market subsequent to the offering or that an active trading market for the common stock will develop and continue after the offering.

Listing

We have submitted an application to list our common stock on The Nasdaq Global Market under the trading symbol "CADL."

Option to Purchase Additional Shares

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase, from time to time, in whole or in part, up to an aggregate of 1,350,000 shares from us at the public offering price set forth on the cover page of this prospectus, less underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to specified conditions, to purchase a number of additional shares proportionate to that underwriter's initial purchase commitment as indicated in the table above. This option may be exercised only if the underwriters sell more shares than the total number set forth on the cover page of this prospectus.

No Sales of Similar Securities

We, our officers, directors and holders of all or substantially all our outstanding capital stock and other securities have agreed, subject to specified exceptions, not to directly or indirectly:

- sell, offer, contract or grant any option to sell (including any short sale), pledge, transfer, establish an open "put equivalent position" within the meaning of Rule 16a-l(h) under the Securities Exchange Act of 1934, as amended; or
- otherwise dispose of any shares of common stock, options or warrants to acquire shares of common stock, or securities exchangeable or exercisable for or convertible into shares of common stock currently or hereafter owned either of record or beneficially; or

- publicly announce an intention to do any of the foregoing for a period of 180 days after the date of this prospectus without the prior written consent of the representatives.

This restriction terminates after the close of trading of the common stock on and including the 180th day after the date of this prospectus

The representatives may, together in their sole discretion and at any time or from time to time before the termination of the 180-day period release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our stockholders who will execute a lock-up agreement, providing consent to the sale of shares prior to the expiration of the lock-up period.

Stabilization

The underwriters have advised us that, pursuant to Regulation M under the Securities Exchange Act of 1934, as amended, certain persons participating in the offering may engage in short sale transactions, stabilizing transactions, syndicate covering transactions or the imposition of penalty bids in connection with this offering. These activities may have the effect of stabilizing or maintaining the market price of the common stock at a level above that which might otherwise prevail in the open market. Establishing short sales positions may involve either “covered” short sales or “naked” short sales.

“Covered” short sales are sales made in an amount not greater than the underwriters’ option to purchase additional shares of our common stock in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional shares of our common stock or purchasing shares of our common stock in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option to purchase additional shares.

“Naked” short sales are sales in excess of the option to purchase additional shares of our common stock. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of shares of common stock on behalf of the underwriters for the purpose of fixing or maintaining the price of the common stock. A syndicate covering transaction is the bid for or the purchase of shares of common stock on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the offering. Similar to other purchase transactions, the underwriter’s purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the common stock originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. The underwriters are not obligated to engage in these activities and, if commenced, any of the activities may be discontinued at any time.

The underwriters may also engage in passive market making transactions in our common stock on The Nasdaq Global Market in accordance with Rule 103 of Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker’s bid, that bid must then be lowered when specified purchase limits are exceeded.

Electronic Distribution

A prospectus in electronic format may be made available by e-mail or on the web sites or through online services maintained by one or more of the underwriters or their affiliates. In those cases, prospective investors may view offering terms online and may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares of common stock for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' web sites and any information contained in any other web site maintained by any of the underwriters is not part of this prospectus, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors.

Directed Share Program

At our request, the underwriters have reserved for sale at the initial public offering price up to 5% of the shares offered by this prospectus for sale at the initial public offering price in a directed share program for employees, directors and other persons associated with us who have expressed an interest in purchasing shares in the offering. The number of shares of common stock available for sale to the general public in the offering will be reduced to the extent these persons purchase the directed shares in the program. Any directed shares not so purchased will be offered by the underwriters to the general public on the same terms as the other shares. Directed shares purchased in the program will not be subject to a lock-up restriction, with the exception of directed shares purchased by our directors and officers, which will be subject to a 180-day lock-up restriction. The representatives in their sole discretion may release any of the shares subject to these lock-up restrictions at any time. We have agreed to indemnify the underwriters against certain liabilities and expenses, including liabilities under the Securities Act, in connection with sales of the directed shares.

Other Activities and Relationships

The underwriters and certain of their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and certain of their respective affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and certain of their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own accounts and for the accounts of their respective customers, and such investment and securities activities may involve securities and/or instruments issued by us and our affiliates. If the underwriters or their respective affiliates have a lending relationship with us, they routinely hedge their credit exposure to us consistent with their customary risk management policies. The underwriters and their respective affiliates may hedge such exposure by entering into transactions which consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities of our affiliates, including potentially the common stock offered hereby. Any such short positions could adversely affect future trading prices of the common stock offered hereby. The underwriters and certain of their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Selling Restrictions

Canada

Resale Restrictions

The distribution of shares of our common stock in Canada is being made only in the provinces of Ontario, Quebec, Alberta, British Columbia, Manitoba, New Brunswick and Nova Scotia on a private placement basis exempt from the requirement that we prepare and file a prospectus with the securities regulatory authorities in each province where trades of these securities are made. Any resale of the shares of common stock in Canada must be made under

applicable securities laws which may vary depending on the relevant jurisdiction, and which may require resales to be made under available statutory exemptions or under a discretionary exemption granted by the applicable Canadian securities regulatory authority. Purchasers are advised to seek legal advice prior to any resale of the securities.

Representations of Canadian Purchasers

By purchasing shares of our common stock in Canada and accepting delivery of a purchase confirmation, a purchaser is representing to us and the dealer from whom the purchase confirmation is received that:

- the purchaser is entitled under applicable provincial securities laws to purchase the shares of common stock without the benefit of a prospectus qualified under those securities laws as it is an "accredited investor" as defined under National Instrument 45-106—*Prospectus Exemptions or Section 73.3(1) of the Securities Act (Ontario), as applicable*,
- the purchaser is a "permitted client" as defined in National Instrument 31-103—*Registration Requirements, Exemptions and Ongoing Registrant Obligations*,
- where required by law, the purchaser is purchasing as principal and not as agent, and
- the purchaser has reviewed the text above under Resale Restrictions.

Conflicts of Interest

Canadian purchasers are hereby notified that certain of the underwriters are relying on the exemption set out in section 3A.3 or 3A.4, if applicable, of National Instrument 33-105—*Underwriting Conflicts* from having to provide certain conflict of interest disclosure in this prospectus.

Statutory Rights of Action

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if the prospectus (including any amendment thereto) such as this prospectus contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser of these securities in Canada should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Enforcement of Legal Rights

All of our directors and officers as well as the experts named herein may be located outside of Canada and, as a result, it may not be possible for Canadian purchasers to effect service of process within Canada upon us or those persons. All or a substantial portion of our assets and the assets of those persons may be located outside of Canada and, as a result, it may not be possible to satisfy a judgment against us or those persons in Canada or to enforce a judgment obtained in Canadian courts against us or those persons outside of Canada.

Taxation and Eligibility for Investment

Canadian purchasers of our shares of common stock should consult their own legal and tax advisors with respect to the tax consequences of an investment in the shares in their particular circumstances and about the eligibility of the shares for investment by the purchaser under relevant Canadian legislation.

Australia

This prospectus is not a disclosure document for the purposes of Australia's Corporations Act 2001 (Cth) of Australia, or Corporations Act, has not been lodged with the Australian Securities & Investments Commission and is only directed to the categories of exempt persons set out below. Accordingly, if you receive this prospectus in Australia:

You confirm and warrant that you are either:

- a "sophisticated investor" under section 708(8)(a) or (b) of the Corporations Act;
- a "sophisticated investor" under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant's certificate to the company which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made; or

- a “professional investor” within the meaning of section 708(11)(a) or (b) of the Corporations Act.

To the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor or professional investor under the Corporations Act any offer made to you under this prospectus is void and incapable of acceptance.

You warrant and agree that you will not offer any of the shares issued to you pursuant to this prospectus for resale in Australia within 12 months of those securities being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

European Economic Area

In relation to each Member State of the European Economic Area (each, a “Relevant State”), no shares have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares which have been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that the shares may be offered to the public in that Relevant State at any time:

- to any legal entity which is a “qualified investor” as defined under Article 2(e) of the Prospectus Regulation;
- to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the Prospectus Regulation), subject to obtaining the prior consent of representatives for any such offer; or
- in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of the shares shall require the Company or any of the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an “offer to the public” in relation to the shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129 (as amended).

This European Economic Area selling restriction is in addition to any other selling restrictions set out below.

PRC

This prospectus has not been and will not be circulated or distributed in the PRC, and no securities may be offered or sold, or will be offered or sold, to any person for re-offering or resale, directly or indirectly, to any resident of the PRC except pursuant to applicable laws and regulations of the PRC.

Hong Kong

No securities have been offered or sold, and no securities may be offered or sold, in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell shares or debentures, whether as principal or agent; or to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong, or SFO, and any rules made under that Ordinance; or in other circumstances which do not result in the document being a “prospectus” as defined in the Companies Ordinance (Cap. 32) of Hong Kong, or CO, or which do not constitute an offer to the public for the purpose of the CO or the SFO. No document, invitation or advertisement relating to the securities has been issued or may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” as defined in the SFO and any rules made under that Ordinance.

This prospectus has not been registered with the Registrar of Companies in Hong Kong. Accordingly, this prospectus may not be issued, circulated or distributed in Hong Kong, and the securities may not be offered for subscription to members of the public in Hong Kong. Each person acquiring the securities will be required, and is deemed by the

acquisition of the securities, to confirm that he is aware of the restriction on offers of the securities described in this prospectus and the relevant offering documents and that he is not acquiring, and has not been offered any securities in circumstances that contravene any such restrictions.

Israel

This prospectus does not constitute a prospectus under the Israeli Securities Law, 5728-1968, or the Securities Law, and has not been filed with or approved by the Israel Securities Authority. In the State of Israel, this prospectus is being distributed only to, and is directed only at, and any offer of the shares is directed only at, (i) a limited number of persons in accordance with section 15A of the Securities Law and (ii) investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and "qualified individuals", each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case purchasing for their own accounts or, where permitted under the Addendum, for the accounts of their respective clients who are investors listed in the Addendum). Qualified investors will be required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

Japan

The offering has not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948 of Japan, as amended), or FIEL, and the Initial Purchaser will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means, unless otherwise provided herein, any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the FIEL and any other applicable laws, regulations and ministerial guidelines of Japan.

Singapore

This prospectus has not been and will not be lodged or registered with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or the invitation for subscription or purchase of the securities may not be issued, circulated or distributed, nor may the securities be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to the public or any member of the public in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person as defined under Section 275(2), or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions, specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of any other applicable provision of the SFA.

Where the securities are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a corporation (which is not an accredited investor as defined under Section 4A of the SFA) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor,

securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares of common stock pursuant to an offer made under Section 275 of the SFA except:

- to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- where no consideration is or will be given for the transfer;
- where the transfer is by operation of law;
- as specified in Section 276(7) of the SFA; or

- as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

Switzerland

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this prospectus nor any other offering or marketing material relating to the offering, the Company or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of securities.

United Kingdom

No shares have been offered or will be offered pursuant to the offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the Shares which has been approved by the Financial Conduct Authority, except that the shares may be offered to the public in the United Kingdom at any time:

(a) to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or

(c) in any other circumstances falling within Section 86 of the FSMA,

provided that no such offer of the shares shall require the Issuer or any Manager to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation. For the purposes of this provision, the expression an “offer to the public” in relation to the shares in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares and the expression “UK Prospectus Regulation” means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

LEGAL MATTERS

The validity of the common stock offered hereby will be passed upon for us by Goodwin Procter LLP, Boston, Massachusetts and for the underwriters by Wilmer Cutler Pickering Hale & Dorr LLP, New York, New York.

EXPERTS

The financial statements of Candel Therapeutics, Inc. as of December 31, 2019 and December 31, 2020 and for each of the years ended December 31, 2019 and December 31, 2020 are included herein in reliance upon the report of KPMG LLP, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

Our Independent Registered Public Accounting Firm, KPMG LLP, or KPMG, informed our Audit Committee that a now-former partner at KPMG (the “Individual”) previously located in the office of the lead audit engagement partner of the Company held a financial interest in the Company for an approximate five-week period during the 2019 audit and professional engagement period. SEC independence rules for covered persons prohibit ownership of shares in the Company during any point in the professional engagement period.

The duration of the violation was limited, from June 17, 2019 through July 24, 2019, and the investment was not material to the Individual’s net worth, the Company or KPMG. Additionally, the Individual did not participate in the Company’s audits or have any oversight over members of the audit engagement team conducting the audit.

After careful consideration of the facts and circumstances and the applicable independence rules, KPMG has concluded that (i) the aforementioned matter did not and does not impair its ability to exercise objective and impartial judgment in connection with its audits of the financial statements of the Company; and (ii) a reasonable investor with knowledge of all relevant facts and circumstances would reach the same conclusion. Management and the Audit Committee for the Company concur with KPMG’s conclusions.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 (File Number 333-257444) under the Securities Act with respect to the common stock we are offering in this prospectus. This prospectus does not contain all of the information included in the registration statement. For further information pertaining to us and our common stock, you should refer to the registration statement and to its exhibits. Whenever we make reference in this prospectus to any of our contracts, agreements or other documents, the references are not necessarily complete, and you should refer to the exhibits attached to the registration statement for copies of the actual contract, agreement or other document.

Upon the completion of this offering, we will be subject to informational requirements of the Exchange Act and will file annual, quarterly and current reports, proxy statements and other information with the SEC. You can read our SEC filings, including the registration statement, at the SEC's website at www.sec.gov. We also maintain a website at www.candeltx.com. Upon completion of this offering, you may access, free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendment to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

INDEX TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Candel Therapeutics, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Candel Therapeutics, Inc. and subsidiary (the Company) as of December 31, 2019 and 2020, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' deficit, and cash flows for each of the years in the two-year period ended December 31, 2020, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2020, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2019

McLean, Virginia
March 29, 2021, except for Note 17 which is as of
July 15, 2021

CANDEL THERAPEUTICS, INC.

Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	DECEMBER 31, 2019	DECEMBER 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 5,179	$ 35,053
Marketable securities	39,878	—
Prepaid expenses and other current assets	153	93
Total current assets	45,210	35,146
Fixed assets, net	425	2,787
Other long-term assets	266	349
Total assets	$ 45,901	$ 38,282
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 218	$ 921
Accrued expenses	1,067	3,142
Paycheck protection program loan	—	463
Other current liabilities	125	187
Total current liabilities	1,410	4,713
Deferred revenue	250	125
Deferred rent	573	632
Warrant liability	2,226	6,831
Long-term debt	420	483
Total liabilities	4,879	12,784
Commitments and contingencies (Note 15)		
Convertible preferred stock:		
Series B convertible preferred stock, $0.01 par value; 11,155,506 shares authorized, issued and outstanding at December 31, 2019 and 2020, liquidation preference of $30,896 at December 31, 2019 and 2020.	26,560	26,560
Series C convertible preferred stock, $0.01 par value; 6,032,170 shares authorized, issued and outstanding at December 31, 2019 and 2020, liquidation preference of $22,500 at December 31, 2019 and 2020.	22,500	22,500
Stockholders' deficit:		
Common stock, $0.01 par value; 75,000,000 shares authorized at December 31, 2019 and 2020. Shares issued and outstanding 11,613,737 and 11,635,096 at December 31, 2019 and 2020, respectively.	116	116
Additional paid-in capital	18,356	20,493
Accumulated other comprehensive loss	(19)	—
Accumulated deficit	(26,491)	(44,171)
Total stockholders' deficit	(8,038)	(23,562)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 45,901	$ 38,282

The accompanying notes are an integral part of these consolidated financial statements.

CANDEL THERAPEUTICS, INC.

Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)

	YEAR ENDED DECEMBER 31,	
	2019	2020
Research and development service revenue, related party	$ 125	$ 125
Operating expenses:		
Research and development	6,607	8,754
General and administrative	2,555	5,181
Total operating expenses	9,162	13,935
Loss from operations	(9,037)	(13,810)
Other income (expense):		
Grant income	571	624
Interest, dividend and investment income (expense), net	1,070	111
Change in fair value of warrant liability	(844)	(4,605)
Total other income (expense), net	797	(3,870)
Net loss	$ (8,240)	$ (17,680)
Other comprehensive (loss):		
Unrealized gain (loss) on available-for-sale securities	(2)	19
Comprehensive loss	$ (8,242)	$ (17,661)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.71)	$ (1.52)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	11,533,718	11,615,208

The accompanying notes are an integral part of these consolidated financial statements.

CANDEL THRAPEUTICS, INC.

Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit

(In thousands, except share and per share amounts)

	SERIES B CONVERTIBLE PREFERRED STOCK		SERIES C CONVERTIBLE PREFERRED STOCK		COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED OTHER COMPREHENSIVE LOSS	ACCUMULATED DEFICIT	STOCKHOLDERS' DEFICIT
	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT				
Balance as of January 1, 2019	11,155,506	$ 26,560	—	$ —	11,613,229	$ 116	$ 17,955	$ (17)	$ (18,251)	$ (197)
Issuance of Series C convertible preferred stock	—	—	6,032,170	22,500	—	—	—	—	—	—
Options exercised	—	—	—	—	508	—	1	—	—	1
Stock-based compensation	—	—	—	—	—	—	400	—	—	400
Unrealized loss on marketable securities	—	—	—	—	—	—	—	(2)	—	(2)
Net loss	—	—	—	—	—	—	—	—	(8,240)	(8,240)
Balance as of December 31, 2019	11,155,506	$ 26,560	6,032,170	$ 22,500	11,613,737	$ 116	$ 18,356	$ (19)	$ (26,491)	$ (8,038)
Options exercised	—	—	—	—	21,359	—	30	—	—	30
Stock-based compensation	—	—	—	—	—	—	1,412	—	—	1,412
Increase in fair value of NC Ohio Trust Warrants	—	—	—	—	—	—	695	—	—	695
Recognition of unrealized loss on marketable securities	—	—	—	—	—	—	—	19	—	19
Net loss	—	—	—	—	—	—	—	—	(17,680)	(17,680)
Balance as of December 31, 2020	11,155,506	$ 26,560	6,032,170	$ 22,500	11,635,096	$ 116	$ 20,493	$ —	$ (44,171)	$ (23,562)

The accompanying notes are an integral part of these consolidated financial statements.

CANDEL THERAPEUTICS, INC.

Consolidated Statements of Cash Flows
(In thousands, except share and per share amounts)

	YEAR ENDED DECEMBER 31,	
	2019	2020
Cash Flows from Operating Activities:		
Net loss	**$ (8,240)**	**$ (17,680)**
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	43	91
Non-cash stock compensation expense	400	2,107
Non-cash interest (income) expense net	—	32
Change in fair value of warrant liability	844	4,605
Write off of IPR&D assets from Periphagen asset acquisition	1,263	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(4)	60
Accounts payable	13	289
Accrued expenses	351	1,512
Deferred revenue	(125)	(125)
Deferred rent	278	121
Other long term assets	—	(83)
Net cash used in operating activities	**(5,177)**	**(9,071)**
Cash Flows from Investing Activities:		
Purchase of available-for-sale securities	(39,107)	(6)
Proceeds from maturities and sales of available-for-sale securities	4,371	39,937
Purchase of Periphagen	(846)	—
Purchase of fixed assets	(159)	(1,476)
Net cash provided by (used in) investing activities	**(35,741)**	**38,455**
Cash Flows from Financing Activities:		
Proceeds from issuance of Series C Preferred	22,500	—
Payment to founders for settlement of related party notes payable	(522)	—
Proceeds from paycheck protection program loan	—	460
Proceeds from option exercises	1	30
Net cash provided by financing activities	**21,979**	**490**
Net increase (decrease) in cash	**(18,939)**	**29,874**
Cash, cash equivalents and restricted cash at beginning of period	**24,384**	**5,445**
Cash, cash equivalents and restricted cash at end of period	**$ 5,445**	**$ 35,319**
Noncash Operating and Investing Activity:		
Leasehold improvements paid by Lessor	$ 294	$ —
Noncash Investing and Financing Activity:		
Assignment of promissory note upon Periphagen acquisition	$ 417	$ —
Supplemental Disclosures of Cash Flow Information:		
Cash paid for taxes	$ 59	$ 93
Capital expenditures in accounts payable and accrued expenses	$ —	$ 977

The accompanying notes are an integral part of these consolidated financial statements.

CANDEL THERAPEUTICS, INC.

Notes to financial statements
(Amounts in thousands, except share and per share amounts)

1. Organization and basis of presentation

Candel Therapeutics, Inc., formerly known as Advantagene, Inc. (the “Company”) is a late clinical stage biotechnology company that was incorporated in Delaware in June 2003. On November 30, 2020, the Company changed its name to Candel Therapeutics, Inc. The Company is focused on helping patients fight cancer with oncolytic viral immunotherapies. The Company’s engineered viruses are designed to induce immunogenic cell death through direct viral – mediated cytotoxicity in cancer cells, thus releasing tumor neo-antigens and creating a pro-inflammatory microenvironment at the site of injection. This approach combines an in-depth knowledge of viral immunotherapy and extensive clinical experience across a wide range of indications. The Company has established two oncolytic viral immunotherapy platforms and our two product candidates, CAN-2409 and CAN-3110, are in clinical trials for a number of tumor types.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if the Company’s product development efforts are successful, it is uncertain when, if ever, the Company will realize revenue from product sales.

The Company has funded its operations primarily with proceeds from the sale of its capital stock and convertible notes. The Company has incurred recurring losses since its inception, including a net loss of $8,240 and $17,680 for the years ended December 31, 2019 and 2020, respectively. In addition, as of December 31, 2020, the Company had an accumulated deficit of $44,171. The Company expects to continue to generate operating losses for the foreseeable future. The future viability of the Company is dependent on its ability to raise additional capital to finance its operations. The Company’s inability to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies. There can be no assurances that additional funding will be available on terms acceptable to the Company, or at all. The Company believes that existing resources will fund planned operations for at least 12 months from the date that these consolidated financial statements were available to be issued.

Accordingly, the consolidated financial statements have been prepared on a basis that assumes the Company continue as a going concern and contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

2. Summary of significant accounting policies

Basis of presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting standards set by the Financial Accounting Standards Board (FASB). The FASB sets generally accepted accounting principles (GAAP) that the Company follows to ensure its financial condition, results of operations, and cash flows are consistently reported. References to GAAP issued by the FASB in these notes to the financial statements are to the FASB *Accounting Standards* Codification (ASC).

Principles of consolidation

The consolidated financial statements include the accounts of Candel Therapeutics, Inc. and its wholly owned subsidiary Candel Therapeutics Securities Corporation. All intercompany transactions and balances have been eliminated.

Emerging growth company

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the ‘Jobs Act”). Under the Jobs Act emerging growth companies can delay adopting new or revised accounting standards

issued subsequent to the enactment of the Jobs Act until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that is (i) no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the Jobs Act. As a result, these consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Use of estimates

The preparation of the Company's consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, and related disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenue and expenses during the reporting period. On an ongoing basis, the Company's management evaluates its estimates, which include but are not limited to management's judgments of accrued expenses, fair value of common stock, valuation of share-based awards, valuations of warrants, fair value of debt and income taxes. Actual results could differ from those estimates.

The Company utilizes significant estimates and assumptions in determining the fair value of its common stock. The Company has utilized various valuation methodologies in accordance with the framework of the American Institute of Certified Public Accountants Technical Practice Aid, Valuation of Privately-Held Company Equity Securities Issued as Compensation (the Practice Aid), to estimate the fair value of its common stock and warrants. Each valuation methodology includes estimates and assumptions that require the Company's judgment. These estimates and assumptions include a number of objective and subjective factors, including external market conditions, the prices at which the Company sold shares of preferred stock, the superior rights and preferences of securities senior to the Company's common stock at the time of, and the likelihood of, achieving a liquidity event, such as an initial public offering or sale. Significant changes to the key assumptions used in the valuations could result in different fair values of common stock at each valuation date.

Comprehensive income (loss)

Components of comprehensive income or loss, including net income or loss, are reported in the consolidated financial statements in the period in which they are recognized. Other comprehensive income or loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net income (loss) and other comprehensive income (loss) are reported net of any related tax effect to arrive at comprehensive income (loss). Comprehensive loss includes net loss as well as other changes in stockholders' equity that result from transactions and economic events other than those with stockholders. For the period presented, the Company had no elements of other comprehensive loss other than its net loss and unrealized loss on marketable securities.

Cash and cash equivalents

The Company considers all highly liquid investments purchased with original final maturities of 90 days or less from the date of purchase to be cash equivalents. Cash and cash equivalents comprise marketable securities with maturities of less than 90 days when purchased. Cash equivalents are reported at fair value.

Marketable securities

Marketable securities at December 31, 2019 consisted of investments in U.S. fixed income mutual funds and corporate debt securities. There were no marketable securities at December 31, 2020. The Company determines the classification of marketable securities at the time of acquisition and evaluates the appropriateness of such classification at each balance sheet date. The marketable securities are classified as available-for-sale pursuant to ASC 320, Investments – Debt and Equity Securities. The marketable securities are recorded at fair value with unrealized gains/(loss) included as a component of accumulated other comprehensive gain/(loss), until realized. Realized gains and losses are included in other income. Marketable securities with maturities of less than one year from the balance sheet date are classified as current assets, and marketable securities with maturities greater than one year from the balance sheet date are classified as non-current assets.

Restricted cash

The Company has $266 of restricted cash as of December 31, 2019 and 2020 which represents cash held in a restricted bank account under the terms of the Company's Needham, Massachusetts facility lease, see Note 15.

Restricted cash is included in other long-term assets. The Company's previously reported December 31, 2019 financial statements included $266 of restricted cash in cash and cash equivalents. The Company has changed the presentation of the $266 of restricted cash from cash and cash equivalents to other long-term assets in the accompanying December 31, 2019 consolidated financial statements.

Fair value measurements

Certain assets and liabilities of the Company are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The carrying values of cash and cash equivalents, accounts payable, accrued expenses and Paycheck protection plan loan approximate their fair values due to the short-term nature of these assets and liabilities. Marketable securities are classified as Level 1 measurements (see Note 4). The Company's warrant liability is carried at fair value and is classified as Level 3 measurements. The carrying value of the Company's long-term debt assumed from the Periphagen transaction is classified as Level 3 (See Note 3).

Property and equipment

Property and equipment consist of networking and computer equipment, furniture and fixtures and leasehold improvements. Property and equipment are recorded at cost, and depreciated using the straight-line method over the estimated useful lives of the respective assets:

ASSET	ESTIMATED USEFUL LIFE
Networking and computer equipment	5 years
Furniture and fixtures	5 years
Leasehold improvements	Shorter of the useful life or remaining lease term

Leases

The Company accounts for leases in accordance with ASC 840. Rent expense for leases is recognized on a straight-line basis beginning on the date premises were delivered. Minimum lease payments comprise of only base rent.

Concentrations of credit risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents and marketable securities. Periodically, the Company maintains deposits and investments in accredited financial institutions in-excess of the federally insured limits. The Company deposits its cash in financial institutions with a high credit quality and has not experienced any losses on such accounts and does not believe it is exposed to any unusual credit risk beyond the normal risk associated with commercial banking relationships.

Deferred offering costs

The Company capitalizes certain legal, professional, accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' deficit as a reduction of proceeds generated as a result of the offering. Should a planned equity financing be abandoned, the deferred offering costs

would be expensed immediately as a charge to operating expenses in the consolidated statement of operations. As of December 31, 2020, the Company has included $83 of deferred offering costs in other long-term assets.

Impairment of long-lived assets

Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset group for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset group to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset group are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value, determined based on discounted cash flows. Long-lived assets consist of fixed assets and to date, the Company has not recorded any impairment losses on such long-lived assets.

Revenue recognition

The Company applies Accounting Standards Codification, or ASC, Topic 606, Revenue from Contracts with Customers, (ASC 606). This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and then assesses whether or not each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Research and development costs and accruals

Research and development expenses include salaries and benefits, materials and supplies, preclinical and clinical trial expenses, stock-based compensation expense, depreciation of equipment, contract services and other outside expenses. The Company has entered into various research and development-related contracts with clinical and research institutions, contract research organizations, and other companies. These agreements are generally cancelable, and related payments are recorded as research and development expenses as incurred. Costs of certain development activities, such as manufacturing, pre-clinical and clinical trial expenses, are recognized based on an evaluation of the progress to completion of specific tasks. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid or accrued research and development costs. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are performed. Costs incurred in obtaining technology licenses and intellectual property are charged to research and development expenses as acquired in-process research and development if the technology licensed or intellectual property acquired has not reached technological feasibility and has no alternative future use.

Patent costs

All patent-related costs incurred in connection with preparing, filing, maintaining and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified in general and administrative expenses.

Stock-based compensation

The Company accounts for its stock-based compensation in accordance with ASC Topic 718, *Compensation—Stock Compensation* (ASC 718). ASC 718 requires all share-based payments to employees and directors to be recognized as expense in the consolidated statements of operations and comprehensive loss based on their grant date fair values. In addition, in accordance with FASB Accounting Standards Update (ASU) 2016-09 which identifies areas for simplification of several areas of share-based payment transactions, the Company treats non-employee grants the same as employee grants. The Company estimates the fair value of options granted using the Black-Scholes option pricing model for stock option grants to both employees and non-employees. The Company believes the fair value of the stock options granted to non-employees is more reliably determinable than the fair value of the services provided.

The Black-Scholes option pricing model requires inputs based on certain subjective assumptions, including (a) the expected stock price volatility, (b) the expected term of the award, (c) the risk-free interest rate and (d) expected dividends. Due to the lack of a public market for the Company's common stock and a lack of company-specific historical and implied volatility data, the Company has based its computation of expected volatility on the historical volatility of a representative group of public companies with similar characteristics to the Company, including stage of product development and life science industry focus. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The Company uses the simplified method as prescribed by the SEC Staff Accounting Bulletin No. 107, Share-Based Payment, to calculate the expected term for options granted to employees as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. The expected term is applied to the stock option grant group as a whole, as the Company does not expect substantially different exercise or post-vesting termination behavior among its employee population. For options granted to non-employees, the Company utilizes the contractual term of the share-based payment as the basis for the expected term assumption. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the stock options. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock.

There are significant judgments and estimates inherent in the determination of the fair value of the Company's common stock. These estimates and assumptions include a number of objective and subjective factors, including external market conditions, the prices at which the Company sold shares of preferred stock, the superior rights and preferences of securities senior to its common stock at the time of, and the likelihood of, achieving a liquidity event, such as an initial public offering or sale.

The Company expenses the fair value of its share-based compensation awards to employees and non-employees on a straight-line basis over the requisite service period, which is generally the vesting period.

Government grants

The Company has applied for grants for the reimbursement of expenditures with the National Institutes of Health for certain qualified operating expenditures. The Company recognizes government grants when there is reasonable assurance that the Company will comply with the conditions attached to the grant arrangement and the grant will be received.

Government grants for research and development efforts are recorded as grant income and classified in other income in the statements of operations and comprehensive loss. The Company recognized government grants of $571 and $624 for the years ended December 31, 2019 and 2020, respectively, as a component of other income/(expense), net in the consolidated statements of operations and comprehensive loss.

Income taxes

The Company accounts for income taxes using the asset and liability method in accordance with ASC Topic 740, *Income Taxes* (ASC 740) which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined on the basis of the differences between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of

the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies. At December 31, 2019 and 2020, the Company has concluded that a full valuation allowance is necessary for its deferred tax assets (see Note 12).

The Company accounts for uncertainty in income taxes, by applying the two-step process to determine the amount of tax benefit to be recognized in the financial statements. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax is then assessed as the amount of benefit to be recognized in the consolidated financial statements. The amount of benefits, that may be used, are the largest amounts that have a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Net loss per share

Basic net loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share is computed using the weighted-average number of shares of common stock outstanding during the period and, if dilutive, the weighted-average number of potential shares of common stock. Diluted net loss per share is the same as basic net loss per share for the years ended December 31, 2019 and 2020 since all potential shares of common stock instruments are anti-dilutive as a result of the loss for such periods.

The Company's convertible preferred stock contractually entitles the holders of such shares to participate in dividends but does not contractually require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss, such losses are not allocated to such participating securities. In periods where the Company reports a net loss attributable to common stockholders, diluted net loss per share is the same as basic net loss per share, since dilutive shares of common stock are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss attributable to common stockholders for the years ended December 31, 2019 and 2020.

Recently issued accounting standards

In February 2016, the FASB issued ASU 2016-02, *Leases* ("Topic 842"), which requires an entity to recognize assets and liabilities arising from a lease for both financing and operating leases. The ASU will also require new qualitative and quantitative disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. ASU 2016-02 is effective for fiscal years beginning after December 15, 2021, with early adoption permitted. The Company is currently evaluating the impact ASU 2016-02 will have on its consolidated financial statements.

In August 2020, the FASB issued ASU 2020-06, "Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815 – 40)" ("ASU 2020-06"). ASU 2020-06 simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. The ASU is part of the FASB's simplification initiative, which aims to reduce unnecessary complexity in U.S. GAAP. The ASU's amendments are effective for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. The Company is currently evaluating the impact ASU 2020-06 will have on its consolidated financial statements.

3. Periphagen, Inc. asset acquisition

On December 9, 2019, the Company entered into a series of asset purchase agreements with Periphagen, Inc., a biopharmaceutical company focused on the development of gene therapy vectors. Under the terms of the asset purchase agreements, the Company acquired exclusive rights to technology and intellectual property, a portfolio of virus vectors under development and fixed assets for $846, and the assumption of a $1,000 promissory note. The Company also agreed to the payment of future royalties on license fees received for license of the intellectual property obtained from Periphagen and on net sales of products that incorporate such intellectual property. The promissory note bears a contractual interest rate of 2% compounded annually, with the outstanding balance and accrued interest due upon maturity in November 2027, with no interim installments due. The estimated market rate for the Company

for an unsecured loan with a maturity in November 2027 was determined to be 15.83%. Although the Company does not have a public credit rating, management estimates a CCC credit rating based on the Company's financial position and stage of development. Using the commensurate rate for a CCC rated company and based on the amount due at maturity, the present value of the future cash outflow was determined to be $417 at the transaction date. The total acquisition price was $1,263 which was allocated to the technology platform, intellectual property and virus vectors.

The asset acquisition was accounted for as acquisition of assets that did not meet the definition of a business. The asset acquisition did not constitute a business as substantially all of the fair value of the gross assets acquired was concentrated in the technology platform and virus vectors, which represent a group of similar identifiable assets as of the acquisition date. As of the acquisition date, the assets were deemed to share similar risk characteristics as (1) each of the virus vectors and technology platform were in the early development stages and shared a similar financial, technical and regulatory risk profile, (2) only preliminary indications had been identified for any of the assets and (3) the underlying therapies of the assets were similar in that each was intended to treat an interrelated subset of autoimmune disorders by interrupting biologic mechanisms that otherwise result in inflammation and tissue damage. The acquired assets and liabilities were recorded at their fair values and the Company immediately expensed the fair value of the acquire technology platform, intellectual property and virus vectors in the consolidated statement of operations and comprehensive loss in the amount of $1,263 as the acquired assets represent in-process research and development with no alternative future use.

4. Fair value of financial assets and liabilities

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values:

	FAIR VALUE MEASUREMENTS AS OF DECEMBER 31, 2019 USING:			
	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL
Assets:				
Marketable securities	$39,878	$ —	$ —	$39,878
Total	$39,878	$ —	$ —	$39,878
Liabilities:				
Long-term debt	$ —	$ —	$ 420	$ 420
Warrant liability	—	—	2,226	2,226
Total	$ —	$ —	$ 2,646	$ 2,646

	FAIR VALUE MEASUREMENTS AS OF DECEMBER 31, 2020 USING:			
	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL
Assets:				
Marketable securities	$ —	$ —	$ —	$ —
Total	$ —	$ —	$ —	$ —
Liabilities:				
Long-term debt	$ —	$ —	$ 483	$ 483
Warrant liability	—	—	6,831	6,831
Total	$ —	$ —	$ 7,314	$ 7,314

Valuation of marketable securities

The fair value of mutual funds is based on the daily closing price as reported by the funds, which represent a Level 1 measurement within the fair value hierarchy.

Valuation of long-term debt

The Company's valuation technique used to measure the fair value of the long-term debt assumed from the Periphagen transaction was a present value calculation based upon a credit rating estimated for the Company at the time the debt was assumed. The determined credit rating used by the company was CCC based upon the financial position and stage of the Company. The estimated rate was 15.83% for an unsecured note due in November 2027 for a CCC rated company. The fair value of the long-term debt based on this approach plus the accrued interest represents a Level 3 measurement within the fair value hierarchy.

Valuation of warrant liability

In connection with the Series B Convertible Preferred Stock issuance, the Company issued warrants to purchase shares of common stock of which certain warrants are shown as a liability on the balance sheet, see Note 10. The fair value of the warrant liability was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The fair value of the warrant liability uses various valuation methods, including the Monte Carlo method, the option-pricing method, probability-weighted expected return and the hybrid method, all of which incorporate assumptions and estimates, to value the common stock warrants. The hybrid method is often used when a company is expecting a liquidity event in the near future and is a combination of the option-pricing and probability-weighted expected return methods. Estimates and assumptions impacting the fair value measurement include the fair value per share of the underlying shares of common stock, risk-free interest rate, expected dividend yield, expected volatility of the price of the underlying preferred stock, and the remaining contractual term of the warrants. The most significant assumption in the model impacting the fair value of the common stock warrants is the fair value of the Company's common stock as of each remeasurement date. The Company determines the fair value per share of the underlying common stock by taking into consideration the most recent sales of preferred stock, results obtained from third-party valuations and additional factors that are deemed relevant.

The following table provides a roll forward of the aggregate fair values of the Company's liabilities, for which fair value is determined by Level 3 inputs:

	SERIES B WARRANT LIABILITY	PROMISSORY NOTE
Balance at January 1, 2019	$ 1,382	$ —
Change in fair value	844	—
Acquisition	—	420
Balance at December 31, 2019	$ 2,226	$ 420
Change in fair value	4,605	63
Balance at December 31, 2020	$ 6,831	$ 483

5. Marketable securities

Marketable securities at December 31, 2019 consisted of the following:

	AMORTIZED COST	UNREALIZED GAINS	UNREALIZED LOSSES	FAIR VALUE
Current:				
US fixed income mutual fund	$ 39,897	$ —	$ (19)	$ 39,878
	$ 39,897	$ —	$ (19)	$ 39,878

The Company may sell certain of its marketable securities prior to their stated maturities. The maturities of the Company's long-term marketable securities generally range from one to two years. The Company held no marketable securities at December 31, 2020.

6. Fixed assets, net

Fixed assets, net consisted of the following:

	DECEMBER 31,	
	2019	2020
Construction in progress	$ —	$1,216
Laboratory equipment	—	1,237
Furniture and fixtures	112	112
Networking and computer equipment	33	47
Leasehold improvements	309	309
Other	14	—
Total fixed assets	$468	$2,921
Less accumulated depreciation	(43)	(134)
Fixed assets, net	$425	$2,787

Depreciation and amortization expense related to the fixed assets was $43 and $91 for the years ended December 31, 2019 and 2020, respectively.

7. Accrued expenses

Accrued expenses consisted of the following:

	DECEMBER 31,	
	2019	2020
Payroll and employee related expenses	$ 577	$1,198
Third-party research and development expenses	401	1,299
Professional fees and other	89	645
	$1,067	$3,142

8. Notes payable

Related party notes payable

During the early years of the Company's operation, its founders, who are currently senior executives and significant shareholders of the Company, personally funded certain Company expenses. The amounts paid by the founders were recorded as notes payable and interest was accrued and compounded at an annual rate of four percent. On November 13, 2018, in connection with the Series B Convertible Preferred Stock financing (see Note 9), the Company entered into an agreement for repayment of these notes payable and accrued interest. The Company paid $1,044 of the outstanding principal and interest with cash, with the remaining balance of $1,045 being repaid through the issuance of 377,130 shares of Series B Convertible Preferred Stock. The Company paid $522 of the cash due to the founders in November 2018, and the remaining $522 was paid in November 2019.

Borrowings under Paycheck Protection Program

On March 27, 2020, President Trump signed the Coronavirus Aid, Relief and Economic Security (the "CARES Act"), which, among other things, outlines the provisions of the Paycheck Protection Program (the "PPP"). Section 1106 of the CARES Act contains provisions for the forgiveness of all or a portion of a PPP loan, subject to the satisfaction of certain requirements. The amount eligible for forgiveness is, subject to certain limitations, the sum of the Company's payroll costs, rent and utilities paid by the Company during the 24-week period beginning on the funding date of the PPP loan.

On April 28, 2020, the Company, as obligor, entered into a promissory note evidencing an unsecured loan in the approximate amount of $460 under the PPP pursuant to the CARES Act. The note matures two years after the date of the loan disbursement and bears interest at a fixed annual rate of 1.00%, with the first six months of principal and interest deferred. Under the terms of the CARES Act, as amended by the Flexibility Act, and the PPP, the Company can apply for and be granted forgiveness for all or a portion of the loan issued under the PPP and the loan is expected to be forgiven to the extent the proceeds are used in accordance with the PPP to cover payroll, mortgage interest, rent, and utility costs incurred by the Company over the 24-week period following the loan disbursement date. As of the date of this filing, the Company is in the process of applying for forgiveness and believes that its use of the loan proceeds will meet the conditions for forgiveness under the PPP and expects the loan to be recorded as income when legal forgiveness is obtained.

9. Capital stock

Convertible preferred stock

As of December 31, 2020, the Company has authorized 17,187,676 shares of Preferred Stock (the Preferred Stock) and has designated 11,155,506 shares as Series B Convertible Preferred Stock (Series B Preferred) and 6,032,170 shares as Series C Convertible Preferred Stock (Series C Preferred). Since the Preferred Stock is redeemable upon a liquidation event, which is not considered to be within the Company's control, it has been classified in temporary equity on the accompanying consolidated balance sheets. The carrying value of the Preferred Stock is the proceeds received less issuance costs.

Issuances of Preferred Stock

On November 13, 2018, the Company entered into a Series B Preferred Stock Agreement whereby the Company was authorized to issue 11,155,506 shares of Series B Preferred, $0.01 par value, at a purchase price of $2.7696 per share. The Company issued 9,026,618 shares of Series B Preferred for gross proceeds of $25,000. As further consideration, the purchaser of Series B Preferred received two warrants to purchase, in the aggregate, up to 7,344,982 shares of the common stock of the Company for $6.81 per share. See Note 10 for description of the warrants issued in connection with the issuance of the Series B Preferred.

In addition, in November 2018, the Company issued 1,751,658 shares of Series B Preferred as payment of convertible notes and 377,130 shares of Series B Preferred as partial repayment of the outstanding related party notes payable, see Note 8.

On March 13, 2019, the Company entered into the Series C Preferred Stock Agreement whereby the Company issued 6,032,170 shares of Series C Preferred, $0.01 par value, at a purchase price of $3.73 per share for total gross proceeds of $22,500.

The Preferred Stock has the following rights, preferences, privileges and restrictions:

Voting

The holders of Preferred Stock are entitled to vote together with all other holders of the Company's voting stock on an "as converted" basis on all matters submitted to a vote of the holders. The Series B Preferred and Series C Preferred stockholders will vote as separate classes on certain issues that solely affect their rights and privileges.

Conversion

Each share of Preferred Stock is convertible into one share of common stock, subject to change per certain anti-dilution provisions in the Company's charter and the reverse stock split discussed in Note 17(a). All shares of Preferred Stock are subject to a mandatory conversion into common stock upon the closing of the sale of shares of common stock to the public of at least $25,000 in a firm commitment underwritten public offering pursuant an effective registration statement under the Securities act of 1933 or upon a vote by or written consent of the requisite number stockholders, see Note 17.

Liquidation preference

Upon a voluntary or involuntary liquidation, dissolution or winding up of the Company, proceeds would be distributed in the following order:

First, to the holders of the Series C Preferred in an amount for each such share of Series C Preferred equal to the greater of (i) two and one-half times the Series C Preferred original issuance price, plus any dividends declared but

unpaid thereon or (ii) such amount per share as would have been payable had all shares of Series C Preferred been converted into common stock immediately prior to such liquidation event. If the Company has insufficient assets to permit payment of such amounts in full, the assets of the Company will be distributed to the holders of Series C Preferred pro rata in proportion to the amounts to which each such holder would otherwise be entitled.

Second, to the holders of the Series B Preferred in an amount for each such share of Series B Preferred equal to the greater of (i) the Series B Preferred original issuance price, plus any dividends declared but unpaid thereon or (ii) such amount per share as would have been payable had all shares of Series B Preferred been converted into common stock immediately prior to such liquidation event. If the Company has insufficient assets to permit payment of such amounts in full, the assets of the Company will be distributed to the holders of Series B Preferred pro rata in proportion to the amounts to which each such holder would otherwise be entitled.

Third, upon the distribution of liquidation preference amounts in full to the holders of Preferred Stock, the remaining assets of the Company available for distribution to stockholders shall be distributed among the common stock pro rata based on the number of shares of common stock held by such holders.

Redemption

The Preferred Stock is not subject to mandatory redemption except in the case of a merger or sale of the Company that has been approved by greater than 50% of the Series C Preferred and the Series B Preferred.

Common stock

The Company has authorized 75,000,000 shares of $0.01 par value common stock at December 31, 2020 of which 11,635,094 are issued and outstanding. Common shares are voting and dividends may be paid when, as and if declared by the board of directors, subject to the limitations and preferences of the Preferred Stock.

Common stock reserved

The Company has reserved the following shares of common stock for future issuance as of:

	DECEMBER 31,	
	2019	2020
Series B Preferred conversion	4,538,592	4,538,592
Series C Preferred conversion	2,454,196	2,454,196
Stock options outstanding	928,286	4,013,311
Shares available for future grant under stock option plan	652,338	87,042
Warrants	7,632,518	7,632,518
	16,205,930	18,725,659

10. Warrants

The Company has the following warrants outstanding for the purchase of common stock as of December 31, 2019 and 2020:

WARRANT	SHARES OF COMMON STOCK SUBJECT TO WARRANTS	EXERCISE PRICE PER SHARE	EXPIRATION DATES
Series A Warrants	124,796	$ 5.67	April-August 2021
Series B Warrants	3,672,491	$ 6.81	November 2023
Series B Conditional Warrants	3,672,491	$ 6.81	November 2023
NC Ohio Trust	162,740	$ 1.46	March 2029

Series A warrants

In connection with the issuance of Series A Preferred Stock in 2016, the Company issued 220,805 five-year warrants to purchase shares of Series A Preferred Stock at an exercise price of $3.20 per share (the “Series A Warrants”). In

2018 upon the conversion of the Series A Preferred Stock into common stock, the Series A Warrants became exercisable for common stock at an exercise price of $5.67 per share and the number of warrants outstanding increased to 124,796. The Series A Warrants expire between April and August 2021, if not exercised.

Series B warrants

In connection with the November 13, 2018 issuance of Series B Preferred, the Company issued warrants to purchase 3,672,491 shares of common stock for $6.81 per share to the purchaser of the Series B preferred (the “Series B Warrants”) which are exercisable upon issuance. In addition, the Company issued to the same stockholder additional five-year warrants for the purchase of 3,672,491 shares of common for $6.81 per share which are only exercisable in the event that the Company completes a future financing that meets certain financial milestones (the “Conditional Series B Warrants”). The Series B Warrants and the Conditional Series B Warrants contain provisions allowing cashless exercise. The Company recorded the Series B Warrants as a component of stockholder’s equity at the time of issuance at their estimated fair value of $2,124 and recorded the Conditional Series B Warrants as a liability on the consolidated balance sheet as the number of shares used to calculate the settlement is not a fixed number of shares.

The Conditional Series B Warrants are remeasured to their fair value at each reporting date with changes in the fair value recognized as a component of other income (expense), net in the consolidated statements of operations and comprehensive loss. The Company will continue to recognize changes in the fair value of the conditional warrant liability until each Conditional Series B Warrant is exercised, expires or qualifies for equity classification. The Conditional Series B Warrant liability fair value was $2,226 and $6,831 as of December 31, 2019 and 2020, respectively.

NC Ohio trust warrants

On March 20, 2019, the Company established the NC Incorporated Ohio Trust, an irrevocable trust funded by the Company. The beneficiary in the trust agreement has provided past services to the Company for more than 15 years and is a non-employee. The warrant provides the beneficiary the right to purchase 162,740 shares of the Company’s common stock, $0.01 par value at an exercise price of $1.46 per share, subject to adjustments as specified in the warrant agreement. The arrangement is unknown to the beneficiary as the arrangement is a silent trust. The Company recognizes the warrants as compensation expense within the consolidated statement of operations and comprehensive loss when the warrants are granted or at the service inception date if the service inception date precedes the grant date. In the period in which the grant date occurs, cumulative compensation cost shall be adjusted to reflect the cumulative effect of measuring compensation cost based on the fair value at the grant date rather than the fair value previously used at the service inception date or subsequent reporting dates. As of December 31, 2020, a grant date was not established as there was not a mutual understanding of key terms. The Company remeasures the fair value of the award at each reporting date, as the service date preceded the grant date. The value of the warrants as of December 31, 2020 is $695 and was recorded as stock compensation expense within research and development expense and a credit to stockholders’ equity in the consolidated financial statements.

11. Stock options, restricted stock and stock—based compensation

The Company’s 2015 Stock Plan, as amended, (the “2015 Plan”) provides for the Company to sell or issue common shares or restricted common stock, or to grant incentive stock options or nonqualified stock options for the purchase of common stock, to employees, members of the board of directors and consultants of the Company. The 2015 Plan is administered by the board of directors and exercise prices, vesting and other restrictions are determined at its discretion. All stock option grants are non-statutory stock options except option grants to employees (including officers and directors) intended to qualify as incentive stock options under the Internal Revenue Code of 1986, as amended. Incentive stock options may not be granted at less than the fair market value of the Company’s common stock on the date of grant, as determined in good faith by the board of directors at its sole discretion. Nonqualified stock options may be granted at an exercise price established by the board of directors at its sole discretion and the vesting periods may vary. Vesting periods are generally four years and are determined by the board of directors. Stock options become exercisable as they vest. Options granted under the 2015 Plan expire no more than ten years from the date of grant.

As of December 31, 2020, the total number of shares of common stock that may be issued under the 2015 Plan was 4,800,846 shares. As of December 31, 2020, the total number of shares remaining available for future grants was 87,042.

On May 28, 2019, the board of directors approved the reduction of the stock option exercise price to $1.46 per share for all outstanding stock options. The change in exercise price was accounted for as a modification pursuant to ASC 718. The Company measured the incremental compensation cost as the excess of the fair value of the modified award over the fair value of the original award immediately before its terms were modified. The total incremental compensation cost due to the modification was $64 for the year ended December 31, 2019. The incremental compensation cost for unvested instruments was $131.

Stock option activity is summarized as follows:

	NUMBER OF STOCK OPTIONS	WEIGHTED-AVERAGE EXERCISE PRICE	WEIGHTED-AVERAGE REMAINING CONTRACTUAL TERM (IN YEARS)	AGGREGATE INTRINSIC VALUE (IN THOUSANDS)
Outstanding as of January 1, 2019	629,758	$ 5.86	3.89	$ 46
Granted	315,308	1.46	2.23	$ 31
Exercised	(508)	1.46		
Cancelled or forfeited	(16,272)	1.92		
Outstanding as of December 31, 2019	928,286	$ 1.43	3.51	$ 120
Granted	3,221,378	1.55	3.83	$ 10,997
Exercised	(21,359)	1.46		
Cancelled or forfeited	(114,994)	1.46		
Outstanding as of December 31, 2020	4,013,311	$ 1.52	4.45	$ 13,818
Exercisable as of December 31, 2020	920,197	$ 1.48	4.81	$ 3,210
Unvested as of December 31, 2020	3,093,154	$ 1.54	4.33	$ 10,608

The fair value of stock options granted was estimated on the grant date using the Black-Scholes option pricing model based on the following weighted-average assumptions:

	YEAR ENDED DECEMBER 31,	
	2019	2020
Expected option life (years)	5.00 -10.00	5.00 - 10.00
Risk-free interest rate	1.52% - 1.83%	0.45% - 0.92%
Expected volatility	71.10% - 71.42%	74.86% - 89.07%
Expected dividend yield	0%	0%
Exercise price	$1.46	$1.55
Fair value of common stock	$1.46 -$1.55	$1.55 - $4.97

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock.

The total fair value of stock options vested during the years ended December 31, 2019 and 2020 was $377 and $1,199, respectively.

The Company has granted shares of restricted common stock. The fair value of shares of restricted common stock is based on the value of the underlying shares of common stock on the date of grant. The grant date fair value of

restricted stock is expensed over the vesting period of such shares. During the year ended December 31, 2019, 109,472 shares of restricted common stock with a grant date fair value of $0.17 per share vested and all shares of restricted common stock were vested at December 31, 2019.

Stock-based compensation expense for the years ended December 31, 2019 and 2020 was classified in the consolidated statements of operations and comprehensive loss as follows:

	YEAR ENDED DECEMBER 31,	
	2019	2020
Research and development	$138	$ 152
General and administrative	262	1,260
Total stock based compensation expense	$400	$1,412

As of December 31, 2019 and 2020, total unrecognized compensation cost related to the unvested stock-based awards was $648 and $4,778, respectively. The unvested stock-based awards are expected to be recognized over a weighted average period of 3.05 years as of December 31, 2020.

12. Income taxes

Income tax expense for 2019 and 2020 consists of the following:

	YEAR ENDED DECEMBER 31,	
	2019	2020
Current expense (benefit):		
Federal	$ —	$ —
State	—	—
Total current expense (benefit):	—	—
Deferred expense (benefit):		
Federal	—	—
State	—	—
Total deferred expense (benefit):	—	—
Total income tax expense (benefit):	$ —	$ —

A reconciliation of income tax expense at the federal statutory income tax rate to the income tax expense at the Company's effective income tax rate is as follows:

	YEAR ENDED DECEMBER 31,	
	2019	2020
Income at US statutory rate	21.00%	21.00%
Permanent adjustments	-0.63%	-1.07%
Mark to market	-2.15%	-5.47%
State taxes, net of federal benefit	6.23%	6.65%
Valuation allowance	-27.87%	-23.95%
Tax credits	3.42%	2.84%
	0.00%	0.00%

Net deferred tax assets as of December 31, 2019 and 2020 consist of the following:

	YEAR ENDED DECEMBER 31,	
	2019	2020
Net operating losses	$ 4,892	$ 7,934
Intangibles	818	750
Accrued expenses & other	243	777
Deferred revenue	102	68
Credits	1,034	1,789
Total deferred tax assets	7,089	11,318
Valuation allowance	(7,089)	(11,318)
Net deferred tax assets (liability)	$ —	$ —

As of December 31, 2020, the Company has gross federal and state net operating loss carryforwards of approximately $8,815 and $27,635, which begin to expire in 2027 and 2032, respectively. Additionally, the Company has $19,726 of the federal net operating loss carryforwards that can be carried forward indefinitely.

As of December 31, 2020, the Company has gross federal and state credit carryforwards of approximately $1,199 and $746, respectively, which begin to expire in 2036 and 2028, respectively.

Management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which are comprised principally of net operating loss carryforwards and certain tax credits. Management has considered the Company's history of cumulative net losses incurred since inception, as well as its lack of product revenue since inception, and has determined that it is more likely than not that the Company will not realize the benefits of its deferred tax assets. As a result, a full valuation allowance has been established at December 31, 2019 and 2020.

Section 382 of the Internal Revenue Code of 1986, as amended ("Section 382"), contains rules that limit the ability of a company that undergoes in ownership change to utilize its net operating losses ("NOLs") and tax credits existing as of the date of such ownership change. Under the rules, such an ownership change is generally any change in ownership of more than 50% of a company's stock within a rolling three-year period. The rules generally operate by focusing on changes in ownership of all stock considered by the rules as owning, directly or indirectly, 5% or more of the stock of a company and any change in ownership arising from new issuances of stock by the company. The Company has not yet determined if such a limitation would be placed against its available net operating losses. The Company will make such a determination prior to the utilization of any future net operating losses.

A summary of changes in the valuation allowance for deferred tax assets during the year ended December 31, 2019 and 2020 were as follows:

	YEAR ENDED DECEMBER 31,	
	2019	2020
Valuation allowance	$ 4,792	$ 7,089
Increases recorded to income tax provision	2,295	4,248
Increases recorded as a benefit to additional paid in capital	2	—
Increases recorded to income tax provision	—	(19)
Valuation allowance	$ 7,089	$ 11,318

The Company files income tax returns in the United States and various state and local jurisdictions. The federal and state tax returns are generally subject to examination for the years ended December 31, 2014 through December 31, 2020. There are currently no pending tax examinations. To the extent the Company has tax attribute carryforwards, the tax year in which the attribute was generated may still be adjusted upon examination.

13. Exclusive licensing agreement with a related party

In March 2014, the Company entered into an exclusive licensing agreement with Ventagen, LLC ("Ventagen") which provides Ventagen the right to develop products for commercial sale and distribution within Mexico, Belize, Guatemala, Honduras, El Salvador, Costa Rica, Nicaragua, Panama, Colombia, and Bolivia. Ventagen paid the Company $1,000 upon the signing of the agreement and agreed to a fixed future payment to the Company of $2,500. The future payment will be made upon the achievement of $5,000 of sales of an approved product by Ventagen and is subject to reduction if Ventagen's costs to develop an approved product exceeds $4,000. In addition to the upfront payment and the future payment, Ventagen agreed to purchase from the Company all manufactured product that is required for clinical or commercial purposes at a price of cost plus 25% of the wholesale price of the approved product subject to a minimum or maximum price. In the event the Company is unable or unwilling to manufacture supply under the terms of the agreement, Ventagen has the right to manufacture its own supply and will be required to pay a fixed fee per dose sold. The Company also agreed to provide certain services to Ventagen related to Ventagen's development plan. Stockholders of the Company own 49.5% of the voting stock of Ventagen, including 47% by the Company's founders who are currently senior executives and significant stockholders of the Company, and trusts for the benefit of their children.

The Company is recognizing the $1,000 upfront license fee as research and development service revenue, related party, as the Company's license agreement with Ventagen is within the scope of ASC 606. The license agreement met the contract existence criteria and contained distinct, identifiable performance obligations for which the stand-alone selling prices were readily determinable and allocable. The terms of the agreement contained multiple, distinct performance obligations, including transfer of a license for the territory, research and development oversight for the trials run by Ventagen, and clinical data sharing.

The Company estimated the transaction prices, including any variable consideration, at contract inception and determined the fair value of such obligations. The performance obligation associated with the license transfer was satisfied at a point in time, or at contract inception; however, the Company assigned no value to the license transfer. The remaining $1,000 transaction price was allocated between the research and development oversight and clinical data sharing. The Company is recognizing revenue for these obligations over an 8-year period, beginning in 2015, by measuring the progress towards satisfaction of the performance obligations. As clinical oversight and clinical data sharing occurs over the 8—year clinical trial period, the revenue is recognized over the same period in which the cost for these services is incurred.

The Company defers recognition of the portion of the $1,000 non-refundable upfront license fee for the portion of the performance obligations that are not satisfied. The Company recognized revenue of $125 in the years ended December 31, 2019 and 2020. The license agreement includes a $2,500 potential future milestone payment due to the Company upon successful completion of certain separate, distinct events. At this time, the Company cannot estimate when the milestone-related performance obligations are expected to be achieved and will recognize revenue once satisfaction is probable. There was no additional variable consideration, significant financing components, noncash consideration, or consideration payable to the customer in this agreement.

14. Technology license agreement

On January 20, 2018 the Company entered into an exclusive option agreement (the "Option Agreement") with The Brigham and Women's Hospital, Inc., a not-for-profit Massachusetts corporation ("BWH"). Pursuant to the Option Agreement, the Company has obtained the exclusive right from BWH to negotiate an exclusive license to make, develop and commercialize rQNestin, a genetically modified oncolytic herpes simplex virus for the treatment of certain types of cancers. Pursuant to the Option Agreement, the Company will support a clinical trial to be conducted at BWH pursuant to the terms of a clinical trial agreement to be negotiated and the Company has committed to remitting $750 in support of such clinical trial over the course of approximately three years. Upon execution of the Option Agreement, the Company remitted a non-refundable fee of $40 to BWH to be applied toward

the Company's on-going obligations to reimburse patent expenses. The $40 fee paid was expensed and classified in research and development expenses in 2018. In the years ended December 31, 2019 and 2020, the Company expensed $332 and $269, respectively, for startup and patient fees for clinical trials performed by BWH.

On September 15, 2020, the Company exercised the Option Agreement with BWH and entered into an exclusive worldwide patent license agreement with BWH ("the BWH License"). In connection with the BWH License, the Company paid a fee of $100 and agreed to reimburse patent costs incurred by BWH, including $141 paid at the time of entering into the BWH License. Prior to the first commercial sale, the Company is required to pay BWH an annual license fee of $50 beginning following the fourth anniversary of the effective date. The BWH License contains cumulative milestone payments equaling a maximum amount of $39,000 upon the achievement of various clinical, commercial and sales milestones of both primary and secondary products. Following the first commercial sale, the Company is required to pay royalties to BWH, which are paid at an increasing rate as net sales increase, ranging from low single digits to high single digits. In addition, after the first commercial sale, the Company is required to pay BWH a pre-determined fixed annual minimum royalty, which amount may be credited against earned royalties starting in the fourth year following the first commercial sale. The Company is also agreed to pay a single digit royalty rate on net sales of any derived products.

15. Commitments and contingencies

Related party leases

In January 2008, the Company entered into an operating lease agreement with a term through December 31, 2022 with Ellka Holdings, LLC ("Ellka") for the space in which the Company operated in Auburndale, MA. This lease was terminated and a termination payment of $115 was made to Ellka and included in operating expenses for the year ended December 31, 2020. In May 2016, the Company entered into a second lease agreement with Ellka for living space for employees, also in Auburndale, MA which was also was terminated at the end of 2020. Ellka is owned and operated by the company's founders, who are currently senior executives and significant stockholders of the Company, and members of their immediate family.

Facility lease

On February 4, 2019, the Company signed a lease agreement for its new corporate headquarters at 117 Kendrick Street in Needham, Massachusetts. The facility consists of a 15,197 square foot property which houses the corporate, clinical and manufacturing operations for the Company. The lease term ends on August 31, 2026. Prior to occupying the new space, the Company had construction performed to modify the space to meet its needs. The cost of this construction was $294 and was paid for by the landlord provided allowance in the lease agreement. The $294 lease incentive was recorded as deferred rent and is being amortized over the life of the lease.

Total rent expense under these leases was $619 and $936 for the years ended December 31, 2019 and 2020, respectively.

The future minimum lease payments at December 31, 2020, are as follows:

2021	$ 521
2022	567
2023	583
2024	598
2025	613
Thereafter	415
Total minimum lease payments	$3,297

Guarantees

The Company has identified the guarantees described below as disclosable, in accordance with ASC 460, *Guarantees*.

As permitted under Delaware law, the Company indemnifies its officers and directors for certain events or occurrences while the officer or director is, or was, serving at the Company's request in such capacity. The maximum potential amount of future payments the Company could be required to make is unlimited; however, the Company has directors' and officers' insurance coverage that should limit its exposure and enable it to recover a portion of any future amounts paid.

The Company is a party to a number of agreements entered into in the ordinary course of business that contain typical provisions that obligate the Company to indemnify the other parties to such agreements upon the occurrence of certain events. Such indemnification obligations are usually in effect from the date of execution of the applicable agreement for a period equal to the applicable statute of limitations. The aggregate maximum potential future liability of the Company under such indemnification provisions is uncertain.

The Company leases office space under a seven – year noncancelable operating lease. The Company has standard indemnification arrangements under this lease that require it to indemnify the landlord against all costs, expenses, fines, suits, claims, demands, liabilities, and actions directly resulting from any breach, violation, or nonperformance of any covenant or condition of the lease.

As of December 31, 2020, the Company had not experienced any losses related to these indemnification obligations, and no material claims with respect thereto were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related reserves have been established.

Legal proceedings

The Company is not a party to any litigation and does not have contingency reserves established for any litigation liabilities.

16. Net loss per share

Net loss per share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows:

	YEAR ENDED DECEMBER 31,	
Numerator:	**2019**	**2020**
Net loss attributable to common stockholders	$ (8,240)	$ (17,680)
Denominator:		
Weighted-average shares of common stock outstanding-basic and diluted	11,533,718	11,615,208
Net loss per share attributed to common stockholders-basic and diluted	$ (0.71)	$ (1.52)

The Company's potentially dilutive securities have been excluded from the computation of dilutive net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of shares of common stock outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same.

The Company excluded the following potential shares of common stock from the computation of diluted net loss per share attributable to common stockholders because including them would have had an anti-dilutive effect.

	YEAR ENDED DECEMBER 31,	
	2019	**2020**
Series B Preferred (as converted to common stock)	4,538,592	4,538,592
Series C Preferred (as converted to common stock)	2,454,196	2,454,196
Outstanding warrants for common stock	7,632,518	7,632,518
Outstanding stock options (as converted to common stock)	928,286	4,013,311
	15,553,592	18,638,617

17. Subsequent events

(a) Reverse stock split

On July 14, 2021, the Company's board of directors and stockholders approved a one-for 2.4579 reverse stock split of the Company's issued and outstanding common stock and a proportional adjustment to the existing conversion ratios for the outstanding shares of convertible preferred stock which became effective on July 15, 2021. Accordingly, all share and per share amounts for all periods presented in the accompanying consolidated financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect the reverse stock split.

(b) Other

On July 10, 2021, the Company's 2021 Equity Incentive Plan, or the 2021 Plan, was adopted by the board of directors and was approved by the stockholders on July 14, 2021, and will become effective upon the execution of the underwriting agreement related to the IPO and will serve as the successor to the 2015 Plan and reserved 2,054,000 shares of common stock under the 2021 Plan. The 2021 Plan authorizes the award of stock options, restricted stock awards, or RSAs, stock appreciation rights, or SARs, restricted stock units, or RSUs, cash awards, performance awards and stock bonus awards. Under the 2021 Plan, shares of common stock, plus any reserved shares not issued or subject to outstanding grants under the 2015 Plan on the effective date of the 2021 Plan are reserved for issuance pursuant to awards granted under the 2021 Plan. The number of shares reserved for issuance under the 2021 Plan will increase automatically on January 1 of each year from 2022 through 2030 by the number of shares equal to the lesser of 4% of the aggregate number of outstanding shares of common stock as of the immediately preceding December 31, or a number as may be determined by the board of directors.

On July 10, 2021, the Company's 2021 Employee Stock Purchase Plan, or the ESPP, was adopted by the board of directors and was approved by the stockholders on July 14, 2021, and will become effective upon the execution of the underwriting agreement related to the IPO. The Company has initially reserved 293,000 shares of common stock for sale under the ESPP. The aggregate number of shares reserved for sale under the ESPP will increase automatically on January 1st of each of the first ten calendar years after the first offering date by the number of shares equal to the lesser of 1% of the total outstanding shares of common stock as of the immediately preceding December 31 (rounded to the nearest whole share) or a fixed number, or a number of shares as may be determined by the board of directors in any particular year.

CANDEL THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)
(unaudited)

	DECEMBER 31, 2020	MARCH 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 35,053	$ 29,152
Prepaid expenses and other current assets	93	319
Total current assets	35,146	29,471
Fixed assets, net	2,787	4,263
Other long-term assets	349	1,360
Total assets	$ 38,282	$ 35,094
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 921	$ 1,513
Accrued expenses	3,142	3,298
Paycheck protection program loan	463	464
Other current liabilities	187	223
Total current liabilities	4,713	5,498
Deferred revenue	125	94
Deferred rent	632	606
Warrant liability	6,831	6,831
Long-term debt	483	502
Total liabilities	12,784	13,531
Commitments and contingencies (Note 14)		
Convertible preferred stock:		
Series B convertible preferred stock, $0.01 par value; 11,155,506 shares authorized, issued and outstanding at December 31, 2020 and March 31, 2021, liquidation preference of $30,896 at December 31, 2020 and March 31, 2021.	26,560	26,560
Series C convertible preferred stock, $0.01 par value; 6,032,170 shares authorized, issued and outstanding at December 31, 2020 and March 31, 2021, liquidation preference of $22,500 at December 31, 2020 and March 31, 2021.	22,500	22,500
Stockholders' deficit:		
Common stock, $0.01 par value; 75,000,000 shares authorized at December 31, 2020 and March 31, 2021. Shares issued and outstanding 11,635,094 and 11,673,135 at December 31, 2020 and March 31, 2021, respectively.	116	117
Additional paid-in capital	20,493	21,035
Accumulated deficit	(44,171)	(48,649)
Total stockholders' deficit	(23,562)	(27,497)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 38,282	$ 35,094

The accompanying notes are an integral part of these condensed consolidated financial statements.

CANDEL THERAPEUTICS, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)
(unaudited)

	THREE MONTHS ENDED MARCH 31,	
	2020	2021
Research and development service revenue, related party	$ 31	$ 31
Operating expenses:		
Research and development	1,621	2,753
General and administrative	728	1,935
Total operating expenses	2,349	4,688
Loss from operations	(2,318)	(4,657)
Other income (expense):		
Grant income	163	191
Interest, dividend and investment income (expense), net	(72)	(12)
Change in fair value of warrant liability	455	—
Total other income (expense), net	546	179
Net loss	$ (1,772)	$ (4,478)
Other comprehensive (loss):		
Unrealized (loss) on available-for-sale securities	(234)	—
Comprehensive loss	$ (2,006)	$ (4,478)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.15)	$ (0.38)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	11,614,335	11,647,786

The accompanying notes are an integral part of these condensed consolidated financial statements.

CANDEL THERAPEUTICS, INC.

Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit

(In thousands, except share and per share amounts)
(unaudited)

	SERIES B CONVERTIBLE PREFERRED STOCK		SERIES C CONVERTIBLE PREFERRED STOCK		COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED OTHER COMPREHENSIVE LOSS	ACCUMULATED DEFICIT	STOCKHOLDERS' DEFICIT
	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT				
Balance as of January 1, 2020	11,155,506	$ 26,560	6,032,170	$ 22,500	11,613,737	$ 116	$ 18,356	$ (19)	$ (26,491)	$ (8,038)
Options exercised	—	—	—	—	1,017	—	1	—	—	1
Stock-based compensation	—	—	—	—	—	—	(32)	—	—	(32)
Unrealized loss on marketable securities	—	—	—	—	—	—	—	(234)	—	(234)
Net loss	—	—	—	—	—	—	—	—	(1,772)	(1,772)
Balance as of March 31, 2020	11,155,506	$ 26,560	6,032,170	$ 22,500	11,614,754	$ 116	$ 18,325	$ (253)	$ (28,263)	$ (10,075)
Balance January 1, 2021	11,155,506	$ 26,560	6,032,170	$ 22,500	11,635,094	$ 116	$ 20,493	$ —	$ (44,171)	$ (23,562)
Options exercised	—	—	—	—	24,410	1	34	—	—	35
Warrants exercised	—	—	—	—	13,631	—	77	—	—	77
Stock-based compensation	—	—	—	—	—	—	431	—	—	431
Change in fair value of NC Ohio Trust Warrants	—	—	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	(4,478)	(4,478)
Balance as of March 31, 2021	11,155,506	$ 26,560	6,032,170	$ 22,500	11,673,135	$ 117	$ 21,035	$ —	$ (48,649)	$ (27,497)

The accompanying notes are an integral part of these condensed consolidated financial statements.

CANDEL THERAPEUTICS, INC.

Condensed Consolidated Statements of Cash Flows
(In thousands, except share and per share amounts)
(Unaudited)

	THREE MONTHS ENDED MARCH 31,	
	2020	2021
Cash Flows from Operating Activities:		
Net loss	**$ (1,772)**	**$ (4,478)**
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	32	26
Non-cash stock compensation expense	(32)	431
Non-cash interest (income) expense net	16	20
Change in fair value of warrant liability	(455)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	30	(225)
Accounts payable	33	173
Accrued expenses	(63)	(1,275)
Deferred revenue	(31)	(31)
Deferred rent	42	9
Other long term assets	(14)	(277)
Net cash used in operating activities	**(2,214)**	**(5,627)**
Cash Flows from Investing Activities:		
Proceeds from sales and maturities of available-for-sale securities	19,282	—
Purchase of fixed assets	—	(229)
Net cash provided by (used in) investing activities	**19,282**	**(229)**
Cash Flows from Financing Activities:		
Proceeds from warrant exercises	—	77
Proceeds from option exercises	1	35
Net cash provided by financing activities	**1**	**112**
Net increase (decrease) in cash	**17,069**	**(5,744)**
Cash, cash equivalents and restricted cash at beginning of period	**5,445**	**35,319**
Cash, cash equivalents and restricted cash at end of period	**$ 22,514**	**$ 29,575**
Supplemental Disclosures of Cash Flow Information:		
Cash paid for taxes	$ 41	$ 6
Capital expenditures in accounts payable and accrued expenses	$ 24	$ 1,850

The accompanying notes are an integral part of these condensed consolidated financial statements.

CANDEL THERAPEUTICS, INC.

Notes to Condensed Consolidated financial statements
(Amounts in thousands, except share and per share amounts)
(unaudited)

1. Organization and basis of presentation

Candel Therapeutics, Inc., formerly known as Advantagene, Inc. (the "Company") is a late clinical stage biotechnology company that was incorporated in Delaware in June 2003. On November 30, 2020, the Company changed its name to Candel Therapeutics, Inc. The Company is focused on helping patients fight cancer with oncolytic viral immunotherapies. The Company's engineered viruses are designed to induce immunogenic cell death through direct viral – mediated cytotoxicity in cancer cells, thus releasing tumor neo-antigens and creating a pro-inflammatory microenvironment at the site of injection. This approach combines an in-depth knowledge of viral immunotherapy and extensive clinical experience across a wide range of indications. The Company has established two oncolytic viral immunotherapy platforms and our two product candidates, CAN-2409 and CAN-3110, are in clinical trials for a number of tumor types.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will realize revenue from product sales.

The Company has funded its operations primarily with proceeds from the sale of its capital stock and convertible notes. The Company has incurred recurring losses since its inception, including a net loss of $8,240, $17,680 and $4,478 for the years ended December 31, 2019 and 2020 and the three months ended March 31, 2021, respectively. In addition, as of March 31, 2021, the Company had an accumulated deficit of $48,649. The Company expects to continue to generate operating losses for the foreseeable future. The future viability of the Company is dependent on its ability to raise additional capital to finance its operations. The Company's inability to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies. There can be no assurances that additional funding will be available on terms acceptable to the Company, or at all. The Company believes that existing resources will fund planned operations for at least 12 months from the date that these consolidated financial statements were available to be issued.

Accordingly, the condensed consolidated financial statements have been prepared on a basis that assumes the Company continue as a going concern and contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

2. Summary of significant accounting policies

Basis of presentation

The accompanying condensed consolidated financial statements have been prepared in accordance with accounting standards set by the Financial Accounting Standards Board (FASB). The FASB sets generally accepted accounting principles (GAAP) that the Company follows to ensure its financial condition, results of operations, and cash flows are consistently reported. References to GAAP issued by the FASB in these notes to the financial statements are to the FASB *Accounting Standards* Codification (ASC).

Principles of consolidation

The condensed consolidated financial statements include the accounts of Candel Therapeutics, Inc. and its wholly owned subsidiary Candel Therapeutics Securities Corporation. All intercompany transactions and balances have been eliminated.

Emerging growth company

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the 'Jobs Act"). Under the Jobs Act emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the Jobs Act until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that is (i) no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the Jobs Act. As a result, these consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Unaudited Interim Financial Information

The accompanying condensed consolidated balance sheet as of March 31, 2021, the condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2020 and 2021, the condensed consolidated statements of convertible preferred stock and stockholders' deficit for the three months ended March 31, 2020 and 2021, the condensed consolidated statements of cash flows for the three months ended March 31, 2020 and 2021, and the related interim disclosures are unaudited. These unaudited condensed consolidated financial statements include all adjustments necessary, consisting of only normal recurring adjustments, to fairly state the financial position and the results of the Company's operations and cash flows for interim periods in accordance with U.S. GAAP. Interim period results are not necessarily indicative of results of operations or cash flows for a full year or any subsequent interim period. The accompanying condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements included elsewhere in this prospectus.

Use of estimates

The preparation of the Company's condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, and related disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenue and expenses during the reporting period. On an ongoing basis, the Company's management evaluates its estimates, which include but are not limited to management's judgments of accrued expenses, fair value of common stock, valuation of share-based awards, valuations of warrants, fair value of debt and income taxes. Actual results could differ from those estimates.

The Company utilizes significant estimates and assumptions in determining the fair value of its common stock. The Company has utilized various valuation methodologies in accordance with the framework of the American Institute of Certified Public Accountants Technical Practice Aid, Valuation of Privately-Held Company Equity Securities Issued as Compensation (the Practice Aid), to estimate the fair value of its common stock and warrants. Each valuation methodology includes estimates and assumptions that require the Company's judgment. These estimates and assumptions include a number of objective and subjective factors, including external market conditions, the prices at which the Company sold shares of preferred stock, the superior rights and preferences of securities senior to the Company's common stock at the time of, and the likelihood of, achieving a liquidity event, such as an initial public offering or sale. Significant changes to the key assumptions used in the valuations could result in different fair values of common stock at each valuation date.

Comprehensive income (loss)

Components of comprehensive income or loss, including net income or loss, are reported in the condensed consolidated financial statements in the period in which they are recognized. Other comprehensive income or loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net income (loss) and other comprehensive income (loss) are reported net of any related tax effect to arrive at comprehensive income (loss). Comprehensive loss includes net loss as well as other changes in stockholders' equity that result from transactions and economic events other than those with stockholders. For the period presented, the Company had no elements of other comprehensive loss other than its net loss and unrealized loss on marketable securities.

Cash and cash equivalents

The Company considers all highly liquid investments purchased with original final maturities of 90 days or less from the date of purchase to be cash equivalents. Cash and cash equivalents comprise marketable securities with maturities of less than 90 days when purchased. Cash equivalents are reported at fair value.

Restricted cash

The Company has $266 and $423 of restricted cash as of December 31, 2020 and March 31, 2021 which represents cash held in a restricted bank account under the terms of the Company's Needham, Massachusetts facility lease and as security for the Company credit card.

Fair value measurements

Certain assets and liabilities of the Company are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The carrying values of cash and cash equivalents, accounts payable, accrued expenses and Paycheck protection plan loan approximate their fair values due to the short-term nature of these assets and liabilities. The Company's warrant liability is carried at fair value and is classified as Level 3 measurements. The carrying value of the Company's long-term debt assumed from the Periphagen transaction is classified as Level 3 (See Note 3).

Property and equipment

Property and equipment consist of networking and computer equipment, furniture and fixtures and leasehold improvements. Property and equipment are recorded at cost, and depreciated using the straight-line method over the estimated useful lives of the respective assets:

ASSET	ESTIMATED USEFUL LIFE
Networking and computer equipment	5 years
Furniture and fixtures	5 years
Leasehold improvements	Shorter of the useful life or remaining lease term

Leases

The Company accounts for leases in accordance with ASC 840. Rent expense for leases is recognized on a straight-line basis beginning on the date premises were delivered. Minimum lease payments comprise of only base rent.

Concentrations of credit risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents and marketable securities. Periodically, the Company maintains deposits and investments in accredited financial institutions in-excess of the federally insured limits. The Company deposits its cash in financial institutions with a high credit quality and has not experienced any losses on such accounts and does not believe it is exposed to any unusual credit risk beyond the normal risk associated with commercial banking relationships.

Deferred offering costs

The Company capitalizes certain legal, professional, accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After

consummation of the equity financing, these costs are recorded in stockholders' deficit as a reduction of proceeds generated as a result of the offering. Should a planned equity financing be abandoned, the deferred offering costs would be expensed immediately as a charge to operating expenses in the consolidated statement of operations. As of December 31, 2020 and March 31, 2021, the Company has included $83 and $937, respectively, of deferred offering costs in other long-term assets.

Research and development costs and accruals

Research and development expenses include salaries and benefits, materials and supplies, preclinical and clinical trial expenses, stock-based compensation expense, depreciation of equipment, contract services and other outside expenses. The Company has entered into various research and development-related contracts with clinical and research institutions, contract research organizations, and other companies. These agreements are generally cancelable, and related payments are recorded as research and development expenses as incurred. Costs of certain development activities, such as manufacturing, pre-clinical and clinical trial expenses, are recognized based on an evaluation of the progress to completion of specific tasks. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid or accrued research and development costs. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are performed. Costs incurred in obtaining technology licenses and intellectual property are charged to research and development expenses as acquired in-process research and development if the technology licensed or intellectual property acquired has not reached technological feasibility and has no alternative future use.

Net loss per share

Basic net loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share is computed using the weighted-average number of shares of common stock outstanding during the period and, if dilutive, the weighted-average number of potential shares of common stock. Diluted net loss per share is the same as basic net loss per share for the three months ended March 31, 2020 and 2021 since all potential shares of common stock instruments are anti-dilutive as a result of the loss for such periods.

The Company's convertible preferred stock contractually entitles the holders of such shares to participate in dividends but does not contractually require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss, such losses are not allocated to such participating securities. In periods where the Company reports a net loss attributable to common stockholders, diluted net loss per share is the same as basic net loss per share, since dilutive shares of common stock are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss attributable to common stockholders for the three months ended March 31, 2020 and 2021.

3. Fair value of financial assets and liabilities

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values:

	FAIR VALUE MEASUREMENTS AS OF DECEMBER 31, 2020 USING:			
	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL
Liabilities:				
Long-term debt	$ —	$ —	$ 483	$ 483
Warrant liability	—	—	6,831	6,831
Total	$ —	$ —	$ 7,314	$7,314

	FAIR VALUE MEASUREMENTS AS OF MARCH 31, 2021 USING:			
	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL
Liabilities:				
Long-term debt	$ —	$ —	$ 502	$ 502
Warrant liability	—	—	6,831	6,831
Total	$ —	$ —	$ 7,333	$7,333

Valuation of long-term debt

The Company's valuation technique used to measure the fair value of the long-term debt assumed from the Periphagen transaction was a present value calculation based upon a credit rating estimated for the Company at the time the debt was assumed. The determined credit rating used by the company was CCC based upon the financial position and stage of the Company. The estimated rate was 15.83% for an unsecured note due in November 2027 for a CCC rated company. The fair value of the long-term debt based on this approach plus the accrued interest represents a Level 3 measurement within the fair value hierarchy.

Valuation of warrant liability

In connection with the Series B Convertible Preferred Stock issuance, the Company issued warrants to purchase shares of common stock of which certain warrants are shown as a liability on the balance sheet, see Note 8. The fair value of the warrant liability was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The fair value of the warrant liability uses various valuation methods, including the Monte Carlo method, the option-pricing method, probability-weighted expected return and the hybrid method, all of which incorporate assumptions and estimates, to value the common stock warrants. The hybrid method is often used when a company is expecting a liquidity event in the near future and is a combination of the option-pricing and probability-weighted expected return methods. Estimates and assumptions impacting the fair value measurement include the fair value per share of the underlying shares of common stock, risk-free interest rate, expected dividend yield, expected volatility of the price of the underlying preferred stock, and the remaining contractual term of the warrants. The most significant assumption in the model impacting the fair value of the common stock warrants is the fair value of the Company's common stock as of each remeasurement date. The Company determines the fair value per share of the underlying common stock by taking into consideration the most recent sales of preferred stock, results obtained from third-party valuations and additional factors that are deemed relevant.

The following table provides a roll forward of the aggregate fair values of the Company's liabilities, for which fair value is determined by Level 3 inputs:

	SERIES B WARRANT LIABILITY	PROMISSORY NOTE
Balance at December 31, 2019	$ 2,226	$ 420
Change in fair value	4,605	63
Balance at December 31, 2020	$ 6,831	$ 483
Change in fair value	—	19
Balance at March 31, 2021	$ 6,831	$ 502

4. Fixed assets, net

Fixed assets, net consisted of the following:

	DECEMBER 31, 2020	MARCH 31, 2021
Construction in progress	$ 1,216	$ 2,535
Laboratory equipment	1,237	1,416
Furniture and fixtures	112	112
Networking and computer equipment	47	51
Leasehold improvements	309	309
Total fixed assets	$ 2,921	4,423
Less accumulated depreciation	(134)	(160)
Fixed assets, net	$ 2,787	$ 4,263

Depreciation and amortization expense related to the fixed assets was $91, $32 and $26 for the year ended December 31, 2020 and the three months ended March 31, 2020 and 2021, respectively.

5. Accrued expenses

Accrued expenses consisted of the following:

	DECEMBER 31, 2020	MARCH 31, 2021
Payroll and employee related expenses	$ 1,198	$ 463
Third-party research and development expenses	1,299	1,783
Professional fees and other	645	1,052
	$ 3,142	$ 3,298

6. Borrowings under Paycheck Protection Program

On March 27, 2020, President Trump signed the Coronavirus Aid, Relief and Economic Security (the "CARES Act"), which, among other things, outlines the provisions of the Paycheck Protection Program (the "PPP"). Section 1106 of the CARES Act contains provisions for the forgiveness of all or a portion of a PPP loan, subject to the satisfaction of certain requirements. The amount eligible for forgiveness is, subject to certain limitations, the sum of the Company's payroll costs, rent and utilities paid by the Company during the 24-week period beginning on the funding date of the PPP loan.

On April 28, 2020, the Company, as obligor, entered into a promissory note evidencing an unsecured loan in the approximate amount of $460 under the PPP pursuant to the CARES Act. The note matures two years after the date

of the loan disbursement and bears interest at a fixed annual rate of 1.00%, with the first six months of principal and interest deferred. Under the terms of the CARES Act, as amended by the Flexibility Act, and the PPP, the Company can apply for and be granted forgiveness for all or a portion of the loan issued under the PPP and the loan is expected to be forgiven to the extent the proceeds are used in accordance with the PPP to cover payroll, mortgage interest, rent, and utility costs incurred by the Company over the 24-week period following the loan disbursement date. In April 2021, the loan was forgiven.

7. Capital stock

Convertible preferred stock

As of December 31, 2020 and March 31, 2021, the Company has authorized 17,187,676 shares of Preferred Stock (the Preferred Stock) and has designated 11,155,506 shares as Series B Convertible Preferred Stock (Series B Preferred) and 6,032,170 shares as Series C Convertible Preferred Stock (Series C Preferred). Since the Preferred Stock is redeemable upon a liquidation event, which is not considered to be within the Company's control, it has been classified in temporary equity on the accompanying consolidated balance sheets. The carrying value of the Preferred Stock is the proceeds received less issuance costs.

Issuances of Preferred Stock

On November 13, 2018, the Company entered into a Series B Preferred Stock Agreement whereby the Company was authorized to issue 11,155,506 shares of Series B Preferred, $0.01 par value, at a purchase price of $2.7696 per share. The Company issued 9,026,618 shares of Series B Preferred for gross proceeds of $25,000. As further consideration, the purchaser of Series B Preferred received two warrants to purchase, in the aggregate, up to 7,344,982 shares of the common stock of the Company for $6.81 per share. See Note 8 for description of the warrants issued in connection with the issuance of the Series B Preferred.

The Preferred Stock has the following rights, preferences, privileges and restrictions:

Voting

The holders of Preferred Stock are entitled to vote together with all other holders of the Company's voting stock on an "as converted" basis on all matters submitted to a vote of the holders. The Series B Preferred and Series C Preferred stockholders will vote as separate classes on certain issues that solely affect their rights and privileges.

Conversion

Each share of Preferred Stock is convertible into one share of common stock, subject to change per certain anti-dilution provisions in the Company's charter and the reverse stock split discussed in Note 14(a). All shares of Preferred Stock are subject to a mandatory conversion into common stock upon the closing of the sale of shares of common stock to the public of at least $25,000 in a firm commitment underwritten public offering pursuant an effective registration statement under the Securities act of 1933 or upon a vote by or written consent of the requisite number stockholders.

Liquidation preference

Upon a voluntary or involuntary liquidation, dissolution or winding up of the Company, proceeds would be distributed in the following order:

First, to the holders of the Series C Preferred in an amount for each such share of Series C Preferred equal to the greater of (i) two and one-half times the Series C Preferred original issuance price, plus any dividends declared but unpaid thereon or (ii) such amount per share as would have been payable had all shares of Series C Preferred been converted into common stock immediately prior to such liquidation event. If the Company has insufficient assets to permit payment of such amounts in full, the assets of the Company will be distributed to the holders of Series C Preferred pro rata in proportion to the amounts to which each such holder would otherwise be entitled.

Second, to the holders of the Series B Preferred in an amount for each such share of Series B Preferred equal to the greater of (i) the Series B Preferred original issuance price, plus any dividends declared but unpaid thereon or (ii) such amount per share as would have been payable had all shares of Series B Preferred been converted into common stock immediately prior to such liquidation event. If the Company has insufficient assets to permit payment of such amounts in full, the assets of the Company will be distributed to the holders of Series B Preferred pro rata in proportion to the amounts to which each such holder would otherwise be entitled.

Third, upon the distribution of liquidation preference amounts in full to the holders of Preferred Stock, the remaining assets of the Company available for distribution to stockholders shall be distributed among the common stock pro rata based on the number of shares of common stock held by such holders.

Redemption

The Preferred Stock is not subject to mandatory redemption except in the case of a merger or sale of the Company that has been approved by greater than 50% of the Series C Preferred and the Series B Preferred.

Common stock

The Company has authorized 75,000,000 shares of $0.01 par value common stock at December 31, 2020 and March 31, 2021 of which 11,635,094 and 11,673,135 are issued and outstanding as of December 31, 2020 and March 31, 2021, respectively. Common shares are voting and dividends may be paid when, as and if declared by the board of directors, subject to the limitations and preferences of the Preferred Stock.

Common stock reserved

The Company has reserved the following shares of common stock for future issuance as of:

	DECEMBER 31, 2020	MARCH 31, 2021
Series B Preferred conversion	4,538,592	4,538,592
Series C Preferred conversion	2,454,196	2,454,196
Stock options outstanding	4,013,311	4,079,006
Shares available for future grant under stock option plan	87,042	78,307
Warrants	7,632,518	7,618,877
	18,725,659	18,768,978

8. Warrants

The Company has the following warrants outstanding for the purchase of common stock as of March 31, 2021:

WARRANT	SHARES OF COMMON STOCK SUBJECT TO WARRANTS	EXERCISE PRICE PER SHARE	EXPIRATION DATES
Series A Warrants	111,155	$ 5.67	April-August 2021
Series B Warrants	3,672,491	$ 6.81	November 2023
Series B Conditional Warrants	3,672,491	$ 6.81	November 2023
NC Ohio Trust	162,740	$ 1.46	March 2029

Series A warrants

In connection with the issuance of Series A Preferred Stock in 2016, the Company issued 220,805 five-year warrants to purchase shares of Series A Preferred Stock at an exercise price of $3.20 per share (the “Series A Warrants”). In 2018 upon the conversion of the Series A Preferred Stock into common stock, the Series A Warrants became exercisable for common stock at an exercise price of $5.67 per share and the number of warrants outstanding increased to 124,796. The Series A Warrants expire between April and August 2021, if not exercised.

Series B warrants

In connection with the November 13, 2018 issuance of Series B Preferred, the Company issued warrants to purchase 3,672,491 shares of common stock for $6.81 per share to the purchaser of the Series B preferred (the “Series B Warrants”) which are exercisable upon issuance. In addition, the Company issued to the same stockholder additional five-year warrants for the purchase of 3,672,491 shares of common for $6.81 per share which are only exercisable in the event that the Company completes a future financing that meets certain financial milestones (the “Conditional

Series B Warrants"). The Series B Warrants and the Conditional Series B Warrants contain provisions allowing cashless exercise. The Company recorded the Series B Warrants as a component of stockholder's equity at the time of issuance at their estimated fair value of $2,124 and recorded the Conditional Series B Warrants as a liability on the consolidated balance sheet as the number of shares used to calculate the settlement is not a fixed number of shares.

The Conditional Series B Warrants are remeasured to their fair value at each reporting date with changes in the fair value recognized as a component of other income (expense), net in the consolidated statements of operations and comprehensive loss. The Company will continue to recognize changes in the fair value of the conditional warrant liability until each Conditional Series B Warrant is exercised, expires or qualifies for equity classification. The Conditional Series B Warrant liability fair value was $6,831 as of December 31, 2020 and March 31, 2021.

On June 24, 2021, the Company's board of directors approved an amendment to the terms of the Series B Warrant and the Series B Conditional Warrants were amended to extend the expiration date from November 2023 to November 2025. In addition, the Company's board of directors approved an amendment to the terms of the Conditional Series B Warrants such that in the event the future financing milestones are achieved, the warrants would only be exercisable in conjunction with the sale of the Company or in November 2025 through a cashless exercise. These amendments are intended to become effective upon the closing of the Company's proposed initial public offering.

NC Ohio trust warrants

On March 20, 2019, the Company established the NC Incorporated Ohio Trust, an irrevocable trust funded by the Company. The beneficiary in the trust agreement has provided past services to the Company for more than 15 years and is a non-employee. The warrant provides the beneficiary the right to purchase 162,740 shares of the Company's common stock, $0.01 par value at an exercise price of $1.46 per share, subject to adjustments as specified in the warrant agreement. The arrangement is unknown to the beneficiary as the arrangement is a silent trust. The Company recognizes the warrants as compensation expense within the consolidated statement of operations and comprehensive loss when the warrants are granted or at the service inception date if the service inception date precedes the grant date. In the period in which the grant date occurs, cumulative compensation cost shall be adjusted to reflect the cumulative effect of measuring compensation cost based on the fair value at the grant date rather than the fair value previously used at the service inception date or subsequent reporting dates. As of December 31, 2020, a grant date was not established as there was not a mutual understanding of key terms. The Company remeasures the fair value of the award at each reporting date, as the service date preceded the grant date. The value of the warrants for 162,740 shares of common stock was $695 as of December 31, 2020 and March 31, 2021 and was recorded as stock compensation expense within research and development expense and a credit to stockholders' equity in the consolidated financial statements.

9. Stock options, restricted stock and stock—based compensation

The Company's 2015 Stock Plan, as amended, (the "2015 Plan") provides for the Company to sell or issue common shares or restricted common stock, or to grant incentive stock options or nonqualified stock options for the purchase of common stock, to employees, members of the board of directors and consultants of the Company. The 2015 Plan is administered by the board of directors and exercise prices, vesting and other restrictions are determined at its discretion. All stock option grants are non-statutory stock options except option grants to employees (including officers and directors) intended to qualify as incentive stock options under the Internal Revenue Code of 1986, as amended. Incentive stock options may not be granted at less than the fair market value of the Company's common stock on the date of grant, as determined in good faith by the board of directors at its sole discretion. Nonqualified stock options may be granted at an exercise price established by the board of directors at its sole discretion and the vesting periods may vary. Vesting periods are generally four years and are determined by the board of directors. Stock options become exercisable as they vest. Options granted under the 2015 Plan expire no more than ten years from the date of grant.

As of March 31, 2021, the total number of shares of common stock that may be issued under the 2015 Plan was 12,000,000 shares. As of March 31, 2021, the total number of shares remaining available for future grants was 78,307 Stock option activity is summarized as follows:

	NUMBER OF STOCK OPTIONS	WEIGHTED-AVERAGE EXERCISE PRICE	WEIGHTED-AVERAGE REMAINING CONTRACTUAL TERM (IN YEARS)	AGGREGATE INTRINSIC VALUE (IN THOUSANDS)
Outstanding as of December 31, 2020	4,013,311	$ 1.52	4.45	$ 13,818
Granted	90,105	4.97		
Exercised	(24,410)	1.46		
Cancelled or forfeited	—			
Outstanding as of March 31, 2021	4,079,006	$ 1.60	4.32	$ 13,733
Exercisable as of March 31, 2021	955,557	$ 1.48	4.72	$ 3,331
Unvested as of March 31, 2021	3,123,449	$ 1.64	4.17	$ 10,401

The fair value of stock options granted was estimated on the grant date using the Black-Scholes option pricing model based on the following weighted-average assumptions:

	YEAR ENDED DECEMBER 31, 2020	THREE MONTHS ENDED MARCH 31, 2021
Expected option life (years)	5.00 - 10.00	6.25
Risk-free interest rate	0.45% - 0.92%	1.06%
Expected volatility	74.86% - 89.07%	88.33%
Expected dividend yield	0%	0%
Exercise price	$1.55	$4.97
Fair value of common stock	$1.55 - $4.97	$4.97

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock.

The total fair value of stock options vested during the year ended December 31, 2020 and three months ended March 31, 2021 was $1,199 and $207, respectively.

Stock-based compensation expense for the three months ended March 31, 2020 and 2021 was classified in the condensed consolidated statements of operations and comprehensive loss as follows:

	THREE MONTHS ENDED MARCH 31,	
	2020	2021
Research and development	$ (85)	$ 115
General and administrative	53	316
Total stock based compensation expense	$ (32)	$ 431

As of March 31, 2021, total unrecognized compensation cost related to the unvested stock-based awards was $4.9 million. The unvested stock-based awards are expected to be recognized over a weighted average period of 2.90 years as of March 31, 2021.

10. Income taxes

During the three months ended March 31, 2020 and 2021, the Company recorded a full valuation allowance on federal and state deferred tax assets since management does not forecast the Company to be in a profitable position in the near future.

As a result of the COVID-19 pandemic, the Coronavirus Aid, Relief, and Economic Security Act (“CARES Act”) was enacted on March 27, 2020 to provide relief for taxpayers. The CARES Act contain a significant number of provisions that may impact on the Company’s accounting for income taxes. The Company has considered several key corporate provisions within the CARES Act, has evaluated its potential impact and does not anticipate it to impact its income tax positions.

11. Exclusive licensing agreement with a related party

In March 2014, the Company entered into an exclusive licensing agreement with Ventagen, LLC (“Ventagen”) which provides Ventagen the right to develop products for commercial sale and distribution within Mexico, Belize, Guatemala, Honduras, El Salvador, Costa Rica, Nicaragua, Panama, Colombia, and Bolivia. Ventagen paid the Company $1,000 upon the signing of the agreement and agreed to a fixed future payment to the Company of $2,500. The future payment will be made upon the achievement of $5,000 of sales of an approved product by Ventagen and is subject to reduction if Ventagen’s costs to develop an approved product exceeds $4,000. In addition to the upfront payment and the future payment, Ventagen agreed to purchase from the Company all manufactured product that is required for clinical or commercial purposes at a price of cost plus 25% of the wholesale price of the approved product subject to a minimum or maximum price. In the event the Company is unable or unwilling to manufacture supply under the terms of the agreement, Ventagen has the right to manufacture its own supply and will be required to pay a fixed fee per dose sold. The Company also agreed to provide certain services to Ventagen related to Ventagen’s development plan. Stockholders of the Company own 49.5% of the voting stock of Ventagen, including 47% by the Company’s founders who are currently senior executives and significant stockholders of the Company, and trusts for the benefit of their children.

The Company is recognizing the $1,000 upfront license fee as research and development service revenue, related party, as the Company’s license agreement with Ventagen is within the scope of ASC 606. The license agreement met the contract existence criteria and contained distinct, identifiable performance obligations for which the stand-alone selling prices were readily determinable and allocable. The terms of the agreement contained multiple, distinct performance obligations, including transfer of a license for the territory, research and development oversight for the trials run by Ventagen, and clinical data sharing.

The Company estimated the transaction prices, including any variable consideration, at contract inception and determined the fair value of such obligations. The performance obligation associated with the license transfer was satisfied at a point in time, or at contract inception; however, the Company assigned no value to the license transfer. The remaining $1,000 transaction price was allocated between the research and development oversight and clinical data sharing. The Company is recognizing revenue for these obligations over an 8-year period, beginning in 2015, by measuring the progress towards satisfaction of the performance obligations. As clinical oversight and clinical data sharing occurs over the 8—year clinical trial period, the revenue is recognized over the same period in which the cost for these services is incurred.

The Company defers recognition of the portion of the $1,000 non-refundable upfront license fee for the portion of the performance obligations that are not satisfied. The Company recognized revenue of $125 and $31 in the year ended December 31, 2020 and each of the three months ended March 31, 2020 and 2021, respectively. The license agreement includes a $2,500 potential future milestone payment due to the Company upon successful completion of certain separate, distinct events. At this time, the Company cannot estimate when the milestone-related performance obligations are expected to be achieved and will recognize revenue once satisfaction is probable. There was no additional variable consideration, significant financing components, noncash consideration, or consideration payable to the customer in this agreement.

12. Commitments and contingencies

Guarantees

The Company has identified the guarantees described below as disclosable, in accordance with ASC 460, *Guarantees*.

As permitted under Delaware law, the Company indemnifies its officers and directors for certain events or occurrences while the officer or director is, or was, serving at the Company's request in such capacity. The maximum potential amount of future payments the Company could be required to make is unlimited; however, the Company has directors' and officers' insurance coverage that should limit its exposure and enable it to recover a portion of any future amounts paid.

The Company is a party to a number of agreements entered into in the ordinary course of business that contain typical provisions that obligate the Company to indemnify the other parties to such agreements upon the occurrence of certain events. Such indemnification obligations are usually in effect from the date of execution of the applicable agreement for a period equal to the applicable statute of limitations. The aggregate maximum potential future liability of the Company under such indemnification provisions is uncertain.

The Company leases office space under a seven – year noncancelable operating lease. The Company has standard indemnification arrangements under this lease that require it to indemnify the landlord against all costs, expenses, fines, suits, claims, demands, liabilities, and actions directly resulting from any breach, violation, or nonperformance of any covenant or condition of the lease.

As of March 31, 2021, the Company had not experienced any losses related to these indemnification obligations, and no material claims with respect thereto were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related reserves have been established.

Legal proceedings

The Company is not a party to any litigation and does not have contingency reserves established for any litigation liabilities.

13. Net loss per share

Net loss per share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows:

	THREE MONTHS ENDED MARCH 31,	
	2020	2021
Numerator:		
Net loss attributable to common stockholders	$ (1,772)	$ (4,478)
Denominator:		
Weighted-average shares of common stock outstanding-basic and diluted	11,614,335	11,647,786
Net loss per share attributed to common stockholders-basic and diluted	$ (0.15)	$ (0.38)

The Company's potentially dilutive securities have been excluded from the computation of dilutive net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of shares of common stock outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same.

The Company excluded the following potential shares of common stock from the computation of diluted net loss per share attributable to common stockholders because including them would have had an anti-dilutive effect.

	THREE MONTHS ENDED MARCH 31,	
	2020	2021
Series B Preferred (as converted to common stock)	4,538,592	4,538,592
Series C Preferred (as converted to common stock)	2,454,196	2,454,196
Outstanding warrants for common stock	7,632,518	7,618,877
Outstanding stock options (as converted to common stock)	997,317	4,079,006
	15,622,623	18,690,671

14. Subsequent events

(a) Reverse stock split

On July 14, 2021, the Company's board of directors and stockholders approved a one-for 2.4579 reverse stock split of the Company's issued and outstanding common stock and a proportional adjustment to the existing conversion ratios for the outstanding shares of convertible preferred stock which became effective on July 15, 2021. Accordingly, all share and per share amounts for all periods presented in the accompanying consolidated financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect the reverse stock split.

(b) Other

On July 10, 2021, the Company's 2021 Equity Incentive Plan, or the 2021 Plan, was adopted by the board of directors and was approved by the stockholders on July 14, 2021, and will become effective upon the execution of the underwriting agreement related to the IPO and will serve as the successor to the 2015 Plan and reserved 2,054,000 shares of common stock under the 2021 Plan. The 2021 Plan authorizes the award of stock options, restricted stock awards, or RSAs, stock appreciation rights, or SARs, restricted stock units, or RSUs, cash awards, performance awards and stock bonus awards. Under the 2021 Plan, shares of common stock, plus any reserved shares not issued or subject to outstanding grants under the Plan on the effective date of the 2021 Plan are reserved for issuance pursuant to awards granted under the 2015 Plan. The number of shares reserved for issuance under the 2021 Plan will increase automatically on January 1 of each year from 2022 through 2030 by the number of shares equal to the lesser of 4% of the aggregate number of outstanding shares of common stock as of the immediately preceding December 31, or a number as may be determined by the board of directors.

On July 10, 2021, the Company's 2021 Employee Stock Purchase Plan, or the ESPP, was adopted by the board of directors and was approved by the stockholders on July 14, 2021, and will become effective upon the execution of the underwriting agreement related to the IPO. The Company has initially reserved 293,000 shares of common stock for sale under the ESPP. The aggregate number of shares reserved for sale under the ESPP will increase automatically on January 1st of each of the first ten calendar years after the first offering date by the number of shares equal to the lesser of 1% of the total outstanding shares of common stock as of the immediately preceding December 31 (rounded to the nearest whole share) or a fixed number, or a number of shares as may be determined by the board of directors in any particular year.

9,000,000 Shares

Common Stock

Prospectus

Jefferies

Credit Suisse

BMO Capital Markets

UBS Investment Bank